Information Sheet Template (Waiver of Documentation of Informed Consent)

VA Central IRB
VA Institutional Review Board for Multisite Studies

INFORMATION SHEET FOR EFFECT OF EXPANDING (GLOVING) BARRIER PRECAUTIONS FOR REDUCING CLOSTRIDIUM DIFFICILE ACQUISITION (AND INFECTION) IN VA: THE GLORI STUDY

You are being asked to participate in a research study conducted by Dr. Nasia Safdar at the William S. Middleton Memorial Veterans' Hospital (Madison, WI) and Dr. Charlesnika Evans at the Edward Hines Jr. VA Hospital. We are conducting a study to learn more about the spread of a bacteria called *Clostridioides difficile* in patients with and without symptoms of infection. You are being asked to participate because you are currently on a unit that is participating in the study. Your participation in this research study is voluntary. You may choose not to participate or leave the study at any time without penalty or loss of benefits to which you were otherwise entitled. If you have any questions, you may ask the study doctor.

WHY IS THIS STUDY BEING DONE?

By conducting this research, we hope to learn more about transmission of a bacteria called *Clostridioides difficile*, also called *C. difficile*, in patients with and without symptoms of infection. *C. difficile* can live in people's intestines and can cause infections in patients taking antibiotics or who are admitted to the hospital. Not all people who have the C. difficile bacteria will have symptoms. However, because these infections can be dangerous in some people, it is important to understand how these infections spread in healthcare settings. To investigate this question, we will use a laboratory test to look for the *C. difficile* bacteria in patients on this unit, including those who do not have symptoms. We will use results of this study to understand and develop practices to prevent the spread of the bacteria that causes *C. difficile* infection, to help protect patients in healthcare settings. VA Health Services Research and Development is paying for this research study. About 12,000 people will give specimens for this research.

WHAT WILL HAPPEN IF I PARTICIPATE IN THIS STUDY?

If you agree to participate, you will be asked to collect two stool specimens: one at admission to this hospital unit and one at discharge from this hospital unit. These specimens will be tested for *C. difficile.* These specimens will be collected in the patient room and can be collected in either of two ways.

The first way would be to collect a perirectal swab. The perirectal swab sample can be collected by wiping a specimen swab on the skin around the anus; the swabs are not inserted into the anus. The perirectal swab can be collected by research staff, by clinical staff, or on your own (similar to wiping with toilet paper). If the swab is self-collected, we will provide the materials and training you need to collect the swab, and you will be able to collect it at your convenience and in privacy.

The second way would be to collect a stool sample. The stool sample can be collected by having a bowel movement in a specimen container that is placed on the toilet. We will provide the materials and training you need to collect the stool, and you will be able to collect it at your convenience and in privacy.

Your research staff are available to help you with the instructions and answer any questions you have about this process. Neither you nor the hospital staff will be informed of the research test results.

Research staff will also look at your medical records to collect details related to your stay on this hospital unit, current illnesses, chronic conditions, and your past medical history related to *C. difficile* (for example, previous infections), recent visits to healthcare facilities, and basic information about you such as your age, gender, and race.

This research study is expected to take approximately three years, but your individual participation in the project will only occur while you are on this unit. It will take approximately two to three minutes to collect each specimen.

Your participation in this study is voluntary. It is up to you to decide whether or not to take part in this study.

After you agree to participate, you are still free to withdraw at any time and without giving a reason.

Refusing or withdrawing from this study will not involve any penalty or loss of benefits to which you are otherwise entitled and will still receive the same standard of care that you would otherwise receive.

If you withdraw, the investigator may continue to review the data or specimens already collected prior to your withdrawal, but will not collect further information or specimens except from public records.

If you are able, we ask that you please let the VA study investigator know as soon as possible about your decision to withdraw.

ARE THERE ANY RISKS OR DISCOMFORTS?

Any procedure has possible risks and discomforts. Rare, unknown, or unexpected risks also may occur.

Stool specimen collection: Collecting stool samples does not pose any risks to you, and we will give you the supplies and training you need for this collection.

Perirectal swab specimen collection: Collecting perirectal swabs does not pose any risks to you, and we will give you the supplies and training you need for this collection. If the perirectal swab is collected by research or clinical staff, you may feel embarrassed. For your comfort, specimen collection will be performed in your patient room with the privacy curtain drawn.

Personal health information: There is a risk of a possible loss of confidentiality regarding patients' health information, but safeguards have been put in place to reduce this risk.

Risks due to the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

ARE THERE ANY BENEFITS?

We do not know if you will get any benefits from taking part of this research study. However, the information we get from this study might help other hospitalized patients in the future by helping us to understand how to better prevent spread of the C. difficile bacteria.

WHO WILL SEE MY INFORMATION AND HOW WILL IT BE PROTECTED?

We take privacy extremely seriously, and so all research data will be handled with the highest confidentiality and discretion by trained researchers. All samples will have patients' names and all personal information removed. Only authorized and trained study team members will have access to personal information, and they will perform all work following the VA's privacy policy. All research data will be kept in locked cabinets or secure computer files only accessible to authorized research personnel. No study results that could identify you will be shared with others outside of the study. Stool samples or swabs may be stored in a VA laboratory setting following the close of the study, but these samples will not be tied to any of your personal information.

Your specimens and information collected for the study will not be used or distributed for future research studies, even after your name and personal information have been removed. Authorized representatives from the Department of Veterans Affairs or other federal regulatory officials responsible for oversight of human subject protection may review your research data for the purpose of monitoring or managing the conduct of this study.

WILL I RECEIVE ANY PAYMENT IF I PARTICIPATE IN THIS STUDY?

You will receive no payment for your participation.

WHO CAN I TALK TO ABOUT THE STUDY?

In the event of a research related injury, the VA will provide necessary medical treatment at no cost to you unless the injury is due to noncompliance with study procedures. Tell the study doctor if you feel that you have been injured because of being in this research. You can tell the doctor in person or call Dr. Charlesnika Evans at 708-202-4868.

If you have any questions, complaints or concerns about the research, please contact the Research Assistant, Ravyn Jackson at 708-202-8387 x21496, Research Assistant Amanda Vivo at 708-202-8387 x25711, Research Assistant Vanessa Rosales at 708-202-5714, or the Local Site Investigator, Dr. Charlesnika Evans at 708-202-4868.
For information about the rights of research subjects, you may call the VA Hospital Patient Advocate at 708-202-2716.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB) toll free at 1-877-254-3130.

You will be given a copy of this information sheet to keep.