UF | Institutional Review Board
UNIVERSITY of FLORIDA

# *INFORMED CONSENT FORM*
***to Participate in Research, and***

# *AUTHORIZATION*
***to Collect, Use, and Disclose Protected Health Information (PHI)***

## INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

## GENERAL INFORMATION ABOUT THIS STUDY

1. **Name of Participant ("Study Subject")**

   _____

2. **What is the Title of this research study (this "Research Study")?**
   Beta-lactam continuous versus intermittent infusion and associated bacterial resistance and therapy outcomes in critically ill patients with severe pneumonia

3. **Whom do you call if you have questions about this Research Study (the "Study Team")?**

   Principal Investigator: Dr. Charles Peloquin (352) 273-6266

   Other research staff: Drs. Awewura Kwara, Kenneth Rand, Veena Venugopalan, and Cesar Trillo.

4. **Who is paying for this Research Study?**

   The sponsor of this study is the Food and Drug Administration (FDA).

5. **In general, what do you need to know about this Research Study?**

   Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

**a) In general, what is the purpose of the research, how long will you be involved?**

As part of your normal care, your physician has prescribed an antibiotic to be given to you through a vein in your arm. The purpose of this research is to study if there is any difference in your health and safety if this antibiotic is given either as a continuous (never stops) infusion vs an infusion that starts and stops a few times a day, also called an intermittent infusion. Individuals who participate in this study will be involved for up to 4 weeks. This includes receiving the antibiotic prescribed by your doctor for the duration your doctor determines and the collection of saliva or sputum samples twice per week during and after finishing the antibiotic therapy for up to 4 weeks of starting therapy. The monitoring and follow up are all included in the 4-week study participation period. There are no study activities outside of the 4-week study period.

**b) What is involved with your participation, and what are the procedures to be followed in the research?**

If you participate in this research we will collect samples from your respiratory system that is normally collected as part of your care. We will use the sample to screen for the type of bacteria that is in your body. If a certain type of bacteria, called Gram-negative, is found in your body we will ask you to enroll in this study. If you decide to take part in this study, you will be randomly assigned (much like the flip of a coin) to receive either a continuous antibiotic dose group or an intermittent antibiotic dose group. You will have a 50% chance of receiving continuous antibiotic infusion and a 50% chance of receiving intermittent antibiotic infusion. The antibiotic is already prescribed by your doctor who will also decide the number of days you will need to receive the antibiotic. If you are in the continuous group, you will receive a 24-hour continuous dose of antibiotics. If you are in the intermittent group, you will receive a 30-minute dose of antibiotics either every six, eight, twelve, or twenty-four hours depending on how your body responds. All doses are given as infusions which means they are given directly into your bloodstream to fight the bacteria in your body. You will receive the same antibiotic total daily dose regardless of whether you are in the intermittent or continuous dose group. Afterward we will collect a respiratory sample twice a week for up to 4 weeks to determine how much bacteria are left in your body after the antibiotic treatment. You will be on the antibiotic therapy for the duration specified by your doctor, but the respiratory samples collection will continue for up to 4 weeks from starting therapy.

**c) What are the likely risks or discomforts to you?**

There might be some brief discomfort associated with the line insertion (if not already in place) and the collection of the respiratory samples from the breathing tubes (in case you are on the ventilator), however, the respiratory samples will be collected by removing the excess secretions from your respiratory system and this process is done as part of your routine care to prevent the blockage of the breathing tubes. Giving the antibiotic by continuous infusion will need a dedicated line to be infused in blood over 24 hours. The clinical team will need to insert a separate line to

minimize other therapies interruption. The intermittent infusion may introduce the antibiotic amount to your blood quickly and then the amount will start to go down. Both of these infusions are used every day in the hospital and there is no information currently that one infusion may cause more side effects compared to the other.

**d) What are the likely benefits to you or to others from the research?**

The continuous infusion will keep the amount of antibiotic in your blood almost constant without fluctuations compared to the intermittent infusion. On the other hand, the intermittent infusion might be more convenient as it is infused over a short period of time (30 minutes) and so will not occupy the line for 24 hours. However, there is no enough information currently proving that the continuous infusion is more effective than the intermittent infusion or vice versa.

**e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?**

In case you're off the ventilator, we will collect your sputum samples instead of using the ventilator's tubes. There are no other treatment alternatives.

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

***Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study***

## WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

**6. What will be done as part of your normal clinical care (even if you did not participate in this Research Study)?**

If you are intubated, a sample from your airway or your saliva will be sent for testing as per standard of care. More samples may be drawn as per standard of care at the clinician's discretion. Your doctor will start you on intravenous antibiotic to fight the suspected bacteria in your body. You will have your antibiotic blood concentration measured in the first days of therapy, and repeated as needed.

**7. What will be done only because you are in this Research Study?**

You will be assigned to either a continuous antibiotic dose group or an intermittent antibiotic dose group. If you are in the continuous group, you will receive a 24-hour continuous dose of antibiotics. If you are in the intermittent group, you will receive a 30-minute dose of antibiotics either every six, eight, twelve, or twenty-four hours depending on how your body responds. All doses are given as infusions which means they are given directly into your bloodstream. You will receive the same antibiotic total daily dose

regardless of whether you are in the intermittent or continuous dose group. Afterward, we will collect a respiratory sample from your airway or sputum twice a week for up to 4 weeks to determine how much bacteria is left in your body after the antibiotic treatment. We will continue to monitor your health and any side effects of treatment.

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

If you have any questions now or at any time during this Research Study, please contact one of the Research Team members listed in question 3 of this form.

**8. What identifiable health information will be collected about you and how will it be used?**

The Research Team will collect data including your age, sex, chronic illness, your health status including but not limited to: blood pressure, body temperature, breathing rate, tests for infections or organisms that could cause infection, tests done on the secretions collected from the breathing tubes that carries air from the windpipe to the lung, lab results including blood cell counts, and amount of minerals in the blood, medications doses, how much you need the ventilator during the treatment, and report for picture of brain wave activity if done.

The Research Team may collect this information from other healthcare providers, such as laboratories, which are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals or clinics). Other professionals at the University of Florida or Shands Hospital who provide study-related care, and the University of Florida Institutional Review Board (IRB), may also collect your health information.

The Research Team listed in question 3 above will use or share your health information as described below to carry out this research study.

**9. With whom will this health information be shared?**

This health information may be shared with:

- United States governmental agencies which are responsible for overseeing research, such as the Department of Health and Human Services and the Office of Human Research Protections;
- Government agencies which are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.

- Your insurance company for purposes of obtaining payment as per usual care
- The IRB that reviewed this Research Study and ensures your rights as a Study Subject are protected

Otherwise, your identifiable health information will not be shared without your permission unless required by law or a court order. Once your health information is shared with those listed above, it is possible that they could share it without your permission because it would no longer be protected by the federal privacy law. Identifiable health information will not be shared with the study sponsor.

**10. How long will you be in this Research Study?**

Up to 4 weeks. This includes receiving the antibiotic prescribed by your doctor for the duration they choose and the collection of respiratory samples twice per week during and after finishing the antibiotic therapy for up to 4 weeks of starting therapy. The monitoring and follow up are all included in the 4-week study participation period. There are no study activities outside of the 4-week study period.

This Authorization to use and share your health information expires at the end of the study, unless you revoke it (take it back) sooner.

**11. How many people are expected to take part in this Research Study?**

240

## WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

**12. What are the possible discomforts and risks from taking part in this Research Study?**

There might be some brief discomfort associated with the line insertion (if not already in place) and the collection of the respiratory samples from the tubes (in case you are on the ventilator), however, the samples will be collected by removing the excess secretions from your respiratory system and this process is done as part of your routine care to prevent the blockage of the breathing tubes.

If you were randomized to the continuous infusion group, the antibiotic will need a dedicated line to be infused in blood over 24 hours. If the line is not in place and in order not to interrupt other infusions you have as prescribed by your doctor, the clinical team will need to insert a separate line through the vein which might be associated with minor discomfort. If you were randomized to the intermittent infusion group, the amount of antibiotic in your blood may go up quickly and then starts to go down. Both of these infusions are used every day in the hospital and there is no information currently that one infusion may cause more side effects compared to the other. The clinical team will be following you and monitoring your results all the time during your stay.

This Research Study may also include risks that are unknown at this time.

Please note, participating in more than one research study or project may further increase the risks to you. If you are already enrolled in a research study, please inform one of the Research Team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

During the study, the Research Team will notify you of new information that may become available and might affect your decision to remain in the study.

The University of Florida is required by law to protect your health information. Your health information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices, as required by University policy. However, there is a slight risk that information about you could be released inappropriately or accidentally. Depending on the type of information, a release could upset or embarrass you, or possibly affect your ability to get insurance or a job.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the Research Team members listed in question 3 in this form.

**13a. What are the potential benefits to you for taking part in this Research Study?**

Some potential benefits associated with the continuous infusion is that the amount of antibiotic in your blood will remain almost constant without fluctuations compared to the intermittent infusion. On the other hand, the intermittent infusion might be more convenient as it is infused over a short period of time (30 minutes) and so will not occupy the line for 24 hours. However, there is no enough information currently proving that the continuous infusion is more effective than the intermittent infusion or vice versa.

**13b. How could others possibly benefit from this Research Study?**

There may be substantial benefits to the society in general in further optimizing antibiotic doses to prevent the emergence of treatment-resistant bacteria in the future.

**13c. How could the Research Team members benefit from this Research Study?**

In general, presenting research results helps the career of a researcher. Therefore, the Research Team listed in question 3 of this form may benefit if the results of this Research Study are presented at scientific meetings or in scientific journals.

**14. What other choices do you have if you do not want to be in this study?**

Taking part in this research study is voluntary. Your alternative is to not take part in the study. If you choose to not take part, your Healthcare at the University of Florida will not be affected.

You may also refuse to authorize the use of your health information, but if you refuse, you may not be allowed to be in this research study or receive any research-related treatment that is only available in this research study. However, your decision not to sign this Authorization will not affect any other treatment you may be eligible to receive.

**15a. Can you withdraw from this study?**

You may withdraw your consent and stop participating in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. If you decide to withdraw your consent to participate in this Research Study for any reason, please contact the Research Team listed in question 3 of this form. They will tell you how to safely stop your participation.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Research Team listed in question 3 of this form to let them know your decision. If you take back this Authorization, the Research Team may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with a member of the Research Team listed in question #3.

**15b. Can the Principal Investigator withdraw you from this Research Study?**

You may be withdrawn from this Research Study without your consent for the following reasons:

1. You have a serious or unexpected adverse event.
2. You become pregnant.
3. Study doctors decide it is not in your best interest to continue the study.
4. You do not or cannot adhere to the instructions provided to you.
5. The IRB decides to stop the study early.

## WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

**16. If you choose to take part in this Research Study, will it cost you anything?**

There may be costs associated with the healthcare you receive while you are participating in this study. At least one of the protocol-required items, services or procedures that will generate charges at UF Health are considered to be conventional care that you would have received even if you chose not to participate in this study.

In addition, one or more protocol-required items, services or procedures will be provided by the sponsor at no charge to you.

If you receive any healthcare at University of Florida Health that is not related to this study, this care will be billed as usual. If you feel you have received a bill related to this study in error, please contact the Principal Investigator.

**17. Will you be paid for taking part in this Research Study?**

There is no compensation for participating in this research study.

**18. What if you are injured while in this Research Study?**

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.
Please contact one of the research team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

## SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

_____

Signature of Person Obtaining Consent & Authorization Date

**Consenting Adults.** You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

**Adult Consenting for Self.** By signing this form, you voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described above. By signing this form, you are not waiving any of your legal rights.

_____

Signature of Adult Consenting & Authorizing for Self Date

**Parent/Adult Legally Representing the Subject.** By signing this form, you voluntarily give your permission for the person named below to participate in this study. You hereby authorize the collection, use and sharing of protected health information for the person named below as described above. You are not waiving any legal rights for yourself or the person you are legally representing. After your signature, please print your name and your relationship to the subject.

_____

Consent & Authorization Signature of Parent/Legal Representative Date

_____ _____

Print: Name of Legal Representative Print: Relationship to Participant:

_____

Print: Name of Subject:

**Participants Who Cannot Consent But Can Read and/or Understand about the Study.** Although legally you cannot "consent" to be in this study, we need to know if you want to take part. If you decide to take part in this study, and your parent or the person legally responsible for you gives permission, you both need to sign. Your signing below means that you agree to take part (assent). The signature of your parent/legal representative above means he or she gives permission (consent) for you to take part.

_____ _____

Assent Signature of Participant Date