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# MEDICAL FACULTY ASSOCIATES

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THE GEORGE WASHINGTON UNIVERSITY

## Research Consent Form

### Protocolized Care for Early Septic Shock (ProCESS)

GW IRB Reference number: 070724

**Principal Investigator/Study Doctor:** Lakhmir Chawla, MD (202) 715-4570

**Study Coordinator:** Christina Seneff (202) 715-5257

**Sponsor:** The National Institutes of Health (NIH) and The University of Pittsburgh

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#### 1) INTRODUCTION

You are invited to participate in a research study of effective treatment options for patients with septic shock, a condition that causes the body to stop working properly. You are being asked to take part in this research study because you have a serious infection with septic shock. Your participation is entirely voluntary.

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. You do not have to take part in this study to receive care at George Washington University (GWU) Hospital. You may or may not receive any benefit from taking part in this study, however, the research may give us knowledge that may help people in the future.

The investigators listed above are from the Department of Anesthesiology and will be conducting this study. The costs of this research study are paid for by the National Institutes of Health (NIH) in association with the University of Pittsburgh.

Before you decide to participate, please feel free to ask any questions and discuss this study with anyone at GWU, with family and friends, and your personal physician or other health professional. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the Principal Investigator or study staff if you are participating in another research study.

#### 2) WHY IS THIS STUDY BEING DONE?

You are being asked to take part in this study because you have a serious infection with septic shock. Up to half of the people with septic shock die. By engaging in the study, we hope to learn the best way to treat patients with septic shock. Specifically, we are conducting a research study in which we compare three ways of monitoring and treating patients with this condition.

The research will be conducted at the following location(s): the GWU Hospital Emergency Department and the GWU Hospital Intensive Care Unit.

### 3) HOW MANY PEOPLE WILL TAKE PART IN THE STUDY

About 1950 participants at approximately 30 institutions will be asked to take part in this study. You will be one of approximately 100 participants asked to take part at this location.

### 4) WHAT IS INVOLVED IN THIS STUDY?

You will be assigned by chance into one of three treatment plans. In all plans you will receive treatment consisting of a combination of intravenous fluids, heart medications (to strengthen the heartbeat and raise the blood pressure) and possibly, blood transfusions over the course of 6 hours. The only difference between the plans is the use of monitoring devices and subsequent guidelines for the combinations of the fluids, blood transfusions, and medications. We will then check your progress by reviewing your hospital records until you are discharged from the hospital (or hospital day 60, whichever comes first). You may be contacted after hospital discharge regarding long-term survival.

**Treatment Plan #1:** Your doctors will treat you according to their standard treatment plan and without any influence from the study team. A member of the study team will simply observe and record what happens. Because this is the 'usual' care, there are no additional risks associated with this treatment plan.

**Treatment Plan #2:** The study team will insert a small tube, called a 'central venous catheter' (CVC), into a blood vessel near your collarbone. A CVC is typically used when a patient needs closer monitoring of their heart rate and blood pressure. The CVC will be connected to a monitoring device to measure blood pressure and blood oxygen. The study team will use this information to give you fluid, blood, and heart medications in a structured fashion. The central venous catheter to be used in this plan is FDA approved and routinely used in hospitals.

**Treatment Plan #3:** The study team will monitor your blood pressure and blood oxygen with standard equipment (without the CVC in treatment plan #2). The study team will use this information to give you fluid and heart medications in a structured fashion. The CVC (vein tubes used in treatment plan #2) will only be used when the standard IVs (smaller vein tubes) cannot give you the proper amount of fluids and medicines. Blood transfusions will be given according to currently recommended guidelines.

The research is asking if one plan is better than another, and if so, why is one better.

We may also draw small samples of blood (approximately 2 tablespoons or 30-35 ml) and urine at enrollment into the study, and at 6, 24, and 72 hours after enrollment. Patients with sepsis (like you) have increased levels of certain molecules in the body. Sampling will be performed to evaluate if levels of these molecules or the inherited factors that control them (differences in genes) can predict the severity and course of septic shock and guide the management of this illness. Your name and other identifying information will be removed from the samples, which will then be coded and sent to a laboratory at the University of Pittsburgh Medical Center. You will not be told of the results of these tests. No third party, including relatives, personal physicians or insurance companies will have access to the stored samples or information. The maximum amount of blood drawn for the whole study will be about 8 tablespoons or 120-140 ml.

Subjects will be enrolled in this study through December 2010.

**5) HOW LONG WILL I BE IN THIS STUDY?**

The total amount of time you will spend in connection with this study is up to 60 days. You may be contacted regarding long-term survival after hospital discharge.

You always can choose to stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

**6) WHAT ARE THE RISKS OF PARTICIPATING IN THIS STUDY?**

The primary risk associated with participation in this study is a potential breach of confidentiality. Coding study data (removing your name and other identifiers and assigning a study subject number to the study record) and storing it in a secure location will minimize this risk. Additional risks across all treatment plans include those associated with extra blood draws, such as bleeding, bruising, and pain at blood draw site. Study staff will minimize the need for additional blood sampling by using already existing catheters (vein tubes) or coordinating the sampling with other routine laboratory work.

Risks associated with the standard of care invasive lines include bleeding, bruising, a collapsed lung (pneumothorax), and infection. In treatment plans 2 and 3, the risk of CVC complications (vessel puncture resulting in bleeding or severe bruising, or lung puncture resulting in a collection of air or blood in the chest) is less than 2% (less than 2 in 100). The risk of heart puncture is very rare (less than 1%). The risk of a CVC-related infection is less than 3% (less than 3 in 100). The risk of complications with a blood transfusion is less than 0.1% (less than 1 in 1000). The risk of fluid overload (extra fluid build-up) is thought to be less than 5% (less than 5 in 100) but specific numbers are not documented.

If you are randomized to treatment plan #2 and you already have a CVC catheter in place, the study doctor may choose to place the special CVC catheter over the wire used to guide the previous insertion. The risks involved in this re-wiring are the same as (listed above) but occur less frequently than when placing a new CVC catheter.

**7) ARE THERE POTENTIAL BENEFITS TO TAKING PART IN THIS STUDY?**

If you agree to take part in this study there may or may not be direct medical benefit to you. You may benefit from either of the new treatment plans (for example, reduced chance of death).

We hope the information learned from this study will benefit other individuals with a serious infection with septic shock in the future or aid in our understanding of this condition.

We cannot and do not guarantee or promise that you will receive any benefits from this study.

If, during the course of the study, additional new risks are found to be associated with participation, you will be so informed.

**8) WHAT ARE MY OPTIONS?**

You do not have to take part in this study if you do not want to participate. **If you decide to not participate in this study, your doctor will continue to treat you according to their usual treatment plan.** Should you decide to take part and later change your mind, you can do so at anytime. If you decide not to take part in this study, your current and future medical care at GWU Hospital will not be affected in any way.

**9) WILL I RECEIVE PAYMENT FOR BEING IN THIS STUDY?**

You will not be paid for taking part in this study.

**10) WHAT WILL IT COST ME IF I DECIDE TO PARTICIPATE IN THIS STUDY?**

There will be no additional costs to you as a result of taking part in this study. However, routine medical care for your condition (the care you would receive whether or not you were in this study) will be charged to you or your insurance company. You may be responsible for any co-payments and deductibles that are standard for your insurance coverage. You will not be billed for services related solely to the research.

If you have any questions about your insurance coverage or the items you might be required to pay for, please call your insurance representative to discuss this further before making your decision about taking part in the study. You also may contact financial services for information. The contact information for financial services is:

GWU Hospital: 202-715-4410

**11) ARE THE RESEARCHERS BEING PAID FOR THE STUDY?**

The sponsor of the study is paying George Washington University and the Study Doctor and his team for their work in this study.

**12) WHO PAYS FOR MY MEDICAL CARE IF I BECOME ILL OR INJURED BECAUSE OF THE STUDY?**

The researchers have taken steps to minimize the known or expected risks. In spite of all precautions, you still may experience medical complications or side effects from participating in this study. If you believe that you have been injured or have become ill from taking part in this study, you should seek medical treatment right away from GWU Hospital and/or the GWU MFA or through your physician or treatment center of choice. If the research-related injury requires medical care beyond emergency treatment, the costs of this follow-up care will be the responsibility of you, your insurer or third party payor.

You also should promptly notify the study doctor in the event of any illness or injury. You will not receive any financial payments from GWU, GWU Hospital and/or the GWU MFA for any injuries or illnesses. You do not waive any liability rights for personal injury by signing this form.

### **13) WHAT ABOUT CONFIDENTIALITY?**

Your information will be kept as confidential as possible. Access to study records will be limited to those who need the information for purposes of this study, as well as your health care providers should they need access to the information. All records are kept in a secure location and access is limited to research study personnel.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed, unless you give the appropriate authorization.

### **14) HOW WILL MY PRIVACY BE PROTECTED?**

Federal law requires that hospitals, researchers and other healthcare providers (like physicians and labs) protect the privacy of health information that identifies you. This kind of information is known as “protected health information” or “PHI.” This section tells you your rights about your protected health information in the study. This section also lists who you let use, release, and get your protected health information. You are free to not allow these uses and releases by not signing this form. If you do that though, you cannot participate in the study.

Protected health information that may be used and released (disclosed) in this study includes information such as:

- This consent form;
- Your name, address, telephone number and social security number (solely for the purpose of long-term survival follow-up through the services of an Honest Broker)
- Your history of medical conditions including heart, lung and kidney disease, or other significant conditions such as diabetes, cancer or previous surgeries;
- Your vital signs and treatments and medications you are given during the study;
- Results of physical examinations related to your diagnosis of severe sepsis;
- Admissions information such as your symptoms and complaints on arrival to the hospital;
- Laboratory results obtained on specimens collected from you (like blood, urine, tissue);
- Health care expenses and health insurance coverage information.

By signing this form, you allow the use, sharing, copying, and release of your protected health information to carry out the study by:

- the Study Doctor and his or her research team.

You also allow the Study Doctor and his or her research team to release your health information to:

- GWU Institutional Review Board (“IRB”) or its authorized representatives, as well as representatives of the Office of Human Research Protections (OHRP) who may review your records to ensure that your rights as a research subject are protected;
- The sponsor of the study (National Institutes of Health) and any contractors or partners it may have. (research monitors, auditors, and the study’s Data Safety Monitoring Board).
- Research collaborators participating in this multi-site Study at other institutions (The data receiving center(s) responsible for collecting, monitoring and /or analyzing data from all the sites participating in this Study is the University of Pittsburgh)
- Regulatory agencies such as the U.S. Food and Drug Administration (FDA) to review data on the safety and effectiveness of the product that is being tested in this Study and other Federal and state agencies that regulate research
- Accrediting agencies and legal counsel
- Clinical staff who are not involved in the study who may become involved in your care, if it might be relevant to your care; and
- GWU, GWU Hospital or GWU MFA workforce who are involved with the research;

Knowing about my health status after discharge may be helpful to other researchers studying septic shock. I give my permission to be re-contacted in the future by the researchers at the University of Pittsburgh regarding potential participation in other related studies.

I do not give my permission to be contacted in the future

You may request to review or have a copy of your personal health information collected during this study and placed in your medical record. This right to review and copy your personal health information only extends to information that is placed in your medical record; it does not extend to information that is placed in your research record.

This permission does not end unless you cancel it, even if you leave the study. You can cancel this permission any time except where a healthcare provider has already used or released your health information, or relied on your permission to do something. Even if you cancel this authorization, the researchers may still use and disclose protected health information they already have obtained about you as necessary to maintain the integrity or reliability of the research. However, no new PHI or new biological specimens will be collected from you after you revoke your authorization.

To cancel your authorization, you will need to send a letter to Lakhmir Chawla, MD of the GWU Hospital stating that you are canceling your authorization. This letter must be signed and dated and sent to this address: 900 23<sup>rd</sup> Street, NW, Suite G-105, Washington, DC 20037. A copy of this revocation will be provided to the Study Doctor and his or her research team. Not signing this form or later canceling your permission will not affect your health care treatment outside the study, payment for health care from a health plan, or ability to get health plan benefits.

Your protected health information will be treated confidentially to the extent permitted by applicable laws and regulations. Federal law may allow someone who gets your health information from this study to use or release it in some way not discussed in this section and no longer be protected by the HIPAA Privacy Rule.

By signing this form you authorize the Study Doctor and members of the research team to use and share with others (disclose) your PHI for the purpose of this study. If you do not wish to authorize the use or disclosure of your PHI, you cannot participate in this study because your PHI is necessary to conduct this study.

**15) CAN I WITHDRAW FROM THE STUDY LATER?**

You may withdraw from the Study at any time. Leaving the Study will not affect your current or future medical care at GWU. If you choose to no longer be in the study, you should call or write to the Study Doctor right away. If you decide to withdraw from the study after you have received study-related care, you may still be required to have certain follow-up tests and procedures to ensure your safety and health.

**16) CAN I BE TAKEN OFF THE STUDY?**

The study Doctor or sponsor can decide to stop your participation in this study at any time. You could be taken off the study for reasons related solely to you (for example, not following study-related directions from the study Doctor, circumstances that may develop and offer alternatives, or a serious reaction) or because the entire study is stopped. The sponsor may stop the study at any time. The sponsor may also decide to stop the Study Doctor's involvement in this study.

**17) WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**

The Office of Human Research of George Washington University, at telephone number (202) 994-2715, can provide further information about your rights as a research subject. Research related injury should be reported to the Principal Investigator of this study. His telephone number is 202-715-4570. Further information regarding this study may be obtained by contacting the study coordinator, Christina Seneff, at telephone number 202-715-5257. For problems arising evenings or weekends, you may call Christina at 301-643-5801.

**18) CONSENT DOCUMENT**

After you sign this Consent Form, the research team will provide you with a copy. Please keep a copy of this document in case you want to read it again.

**If you agree to participate in this study, please sign below:**

\_\_\_\_\_  
Subject's Name (printed) and Signature Date and **Time**

\_\_\_\_\_  
Name (printed) and Signature of Legally Authorized Representative Date and **Time**

\_\_\_\_\_  
Representative's Relationship to Subject

\_\_\_\_\_  
Name (printed) and Signature of Person Obtaining Consent Date

**INVESTIGATOR STATEMENT**

I certify that the research study has been explained to the above individual by me or my research staff including the purpose, the procedures, the possible risks and the potential benefits associated with participation in this research study. Any questions raised have been answered to the individual's satisfaction.

\_\_\_\_\_  
Principal Investigator's Name (printed) and Signature Date

**DO NOT SIGN AFTER THE EXPIRATION DATE OF: 10 / 23 / 2010**

