
MEDICAL FACULTY ASSOCIATES

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

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

Study Purpose and Procedures: Your doctor thinks you have a serious infection with ‘septic shock’ – a condition that causes the body to stop working properly. We are studying the best way to treat patients with that condition. Specifically, we are conducting a research study, sponsored by the National Institutes of Health (NIH), in which we compare three ways of monitoring and treating patients’ with septic shock.

Your participation in this study is completely voluntary and a decision to participate, or to later withdraw from the study, will not affect either your current or future medical care at GWU.

You will be assigned by chance (randomly) into **one of three** treatment plans. In all plans you will receive treatment consisting of a combination of intravenous fluids, blood transfusions and heart medications (to strengthen the heartbeat and raise the blood pressure) over the course of 6 hours. The only difference between the plans is the use of monitoring devices and treatment 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). The research is asking if one plan is better than another, and if so, why one is better.

We will also draw small samples of blood (approximately 6 teaspoons) 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. Testing will be done to see 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 either to a laboratory at the University of Pittsburgh Medical Center or to a commercial laboratory. You will not be told of the results of these tests. No other third parties, including relatives, personal physicians or insurance companies will have access to the stored samples or information.

Subjects will be enrolled in this study through August 2012.

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 records 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 collar bone. This tube 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 CVC 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 #2). The study team will use this information to give you fluid and heart medications in a structured fashion. Special “central lines” (the CVC used in #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.

After leaving the hospital, you will be contacted by phone, about 90 days after study enrollment for a short quality of life survey which will take about 5 minutes to complete. Your study participation ends after the 90 day follow-up call.

In addition you may be contacted again regarding long-term survival. Contact information will be collected from you and 2 family members and/or friends for this purpose.

Risks and Benefits: The primary risk associated with participation in any arm is a potential breach of confidentiality. This risk will be minimized to the extent possible by coding study data and storing it in a secure location. Additional risks across all arms include those associated with extra blood draws, such as bleeding, bruising and pain at the 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.

In treatment plans #2 & #3, the risk of CVC complications (vessel puncture resulting in bleeding or severe bruising, or the risk of lung puncture resulting in a collection of air or blood in the chest) is less than 2% (< 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% (< 3 in 100). The risk of complications with a blood transfusion is less than 0.1% (< 1 in 1000). The risk of fluid overload (extra fluid build-up) is thought to be less than 5% (<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 catheter.

Costs and Payments: You will not be paid for participating in this study.

If you decide to not participate in this study, your doctor will continue to treat you according to their usual treatment plan for your condition. All the usual standard of care procedures and drugs will be used, as needed, including: IV fluids and medicine to maintain blood pressure; antibiotics; oxygen and breathing assistance, blood products, dialysis, etc.

- **You may benefit from either of the new treatment plans, but there is no guarantee of any benefit.** You will be told about any new risks found to be associated with study participation.

You and your insurer or third party payor will not be billed for research-related services; services related solely to the research will be paid for by the research grant. However, you, or your insurer, will be billed for all other usual care services, and/or services not connected with the study, just as you would if not in the study.

- **If you think that injury or illness has happened to you from being in the study, you may contact Dr. Lakhmir Chawa at 202.715.4570.** 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 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.
- **If the investigators feel that you cannot complete the study requirements safely, they may withdraw you from the study.**
- **To conduct this study properly and carefully monitor your health, we need access to your**

medical records. We will store this information indefinitely, and will keep it as confidential (private) as possible.

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;

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 in order 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 23rd 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.

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.

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

YOU DO NOT GIVE YOUR PERMISSION TO BE CONTACTED IN THE FUTURE.

VOLUNTARY CONSENT:

1. The study has been described to you and your questions have been answered. Any additional questions or concerns about any aspect of this study will be answered by the researchers.
2. Questions you might have about your rights as a research participant will be answered by the Office of Human Research of George Washington University, at telephone number (202) 994-2715.

By signing this form, you agree to participate in this research study. A copy of this consent form will be given to you.

_____	_____	_____	_____
Participant's Name (Print)	Participant's Signature	Date	Time

SURROGATE CONSENT:

_____ is unable to provide direct consent for study participation because
Patient's Name (Print)

Therefore, by signing this form, I give my consent for his/her participation in this research study.

_____	_____	_____	_____
Representative's Name (Print)	Representative's Signature	Date	Time

Relationship to Participant _____

INVESTIGATOR'S CERTIFICATION: I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the subject or their family member and any questions about this information have been answered.

Investigator Signature _____ **Date** _____

DO NOT SIGN ON OR AFTER THE EXPIRATION DATE OF: 10/23/2012

