MEDICAL FACULTY ASSOCIATES

THE GEORGE WASHINGTON UNIVERSITY

RESEARCH CONSENT FORM

Study: ProGReSS AKI and Cardiovascular ConsequenceS: The Long-term Outcomes of Sepsis (ProGReSS AKI and ConsequenceS)

Principal Investigator: Dr. Katrina Hawkins (202) 715-4543

Sponsor: National Institute of Health (NIH)/National Institute of Diabetes and Digestive and Kidney Disease (NIDDK)/National Institute of General Medicine (NIGMS)

You are being asked to participate in this study because you have a serious infection with 'septic shock' or sepsis - a condition that causes the body to stop working properly. Patients with sepsis are at a higher risk for Acute Kidney Injury (AKI). The kidney is an organ in your body that cleans the blood by filtering out waste products and is one of the most common organs to be affected by severe sepsis. As a response to injury, the kidney will produce different proteins which are expressed in your blood and urine.

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 the George Washington University Hospital (GWUH).

Patients with sepsis (like you) have increased levels of certain substances in the body. We are asking your permission to draw blood and collect urine that will be analyzed to evaluate if levels of these substances 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.,

To do this study, we will collect 36 milliliters of blood (approximately 7 teaspoons), and 30 milliliters of urine (approximately 2 tablespoons) at two study time points while you are in the hospital. We will use an existing catheter for this blood draw if one is present.

While you are in the hospital we will collect the following information from you as well:

- Data collection of your in-hospital clinical data (i.e. lab results, vitals, etc.). Data collected will be specific to this observational study using this protocol's primary outcomes. Data will include that obtained for routine clinical care, in particular diagnostic laboratory, vitals and imaging data and physiologic monitoring data. We will be reviewing your hospital records until you are discharged from the hospital (or you have reached 12 days of study enrollment, whichever comes first).
- Obtain your discharge location from the hospital, and any additional family/friend contact information
- You will be asked to sign an authorization for release of medical records

As part of your ProGReSS AKI and ConsequenceS participation, you will receive four in home study visits after you have been discharged from the hospital. The ProGReSS AKI and ConsequenceS coordinating center located at the University of Pittsburgh will contact you to coordinate all home study visits. The home study visits will be conducted by a certified paramedical professional at 3, 6, 12 and 36 months after your enrollment. The visits will be conducted in the privacy of your home, and will require 2-3 hours of your time. These home visits will consist of:

• A physical examination which will involve measuring your height, weight, blood pressure, pulse and assessment of swelling from fluid buildup in your legs and feet.

• A detailed medical history interview with questions regarding medications, recent illness, hospitalizations, tobacco use, alcohol consumption, and drug use. You will be given a questionnaire that will focus on heart, kidney symptoms, lifestyle, sleeping habits. You will be asked to sign an authorization for release of medical records.

• Collection of a small sample of blood from your arm (approximately 4 teaspoons) and urine (approximately 2 tablespoons).

Physical Exam, medical history, interview questionnaires, additional family/friend contact information and authorization for release of medical records will be sent to the University of Pittsburgh. These documents will be uploaded to an electronic database and paper records will be kept as resource data in a locked cabinet in a locked research room within the ProGReSS AKI and ConsequenceS coordinating center.

For the purposes of this study, if we learn through your medical records or listed contact person you have died, the ProGReSS AKI and ConsequenceS research team will: try to obtain a death certificate, review hospital records and conduct a telephone interview with one of the contacts listed.

Blood and urine samples will be collected to evaluate if markers in your blood and urine can predict the onset and recovery of acute kidney injury. Genetic analysis will be performed to evaluate whether the levels of these molecules, markers or the inherited factors (gene differences) that control them can predict the severity and course of septic shock and guide the management of this illness. Results of the genetic analysis will not be shared with you as these measurements will have no effect on your treatment.

Your blood and urine samples will be identified with a code number instead of your name. The key that links your code number to your name will be stored in a locked office. Only the study team will have access to the code link. The coded samples will be sent to the CRISMA Molecular Core Laboratory department located within the University of Pittsburgh. At the CRISMA lab your samples will be stored in a locked freezer under the supervision of the study's principal investigator (Dr. John Kellum). You will not be told of the results of the blood and urine tests, however, if the tests on your blood and urine samples indicate chronic kidney disease (CKD), a letter will be mailed to you and your primary care physician (PCP) explaining this result and its significance. A phone number will be provided so you can contact the study investigators if you, or your PCP, have any questions. Contact information (address/phone number, etc) will also be

obtained from you for two close friends or relatives; this information will be used in cases when we are trying to reach you for the study by phone, and are not successful.

Risks and Benefits: The primary risk associated with participation in this study is a potential breach of confidentiality. Some people worry that genetic information could be used to discriminate against them. To prevent misuse of your data, the researchers will replace your name and other identifying information with a code number that only the study team can link to you and it will be stored in a secured location as a special precaution. In addition, a law was passed in 2008 by the Federal Government that prohibits many forms of discrimination based on genetic information

You understand that your blood sample will be withdrawn by a needle in your arm and carries the possible risks associated with the blood draws such as bleeding, infection, bruising and discomfort at the blood draw site. These risks will be minimized by having a trained and experienced paramedical professional draw your blood sample.

Costs and Payments: There will be no additional costs to you as a result of being in this study. You will be reimbursed $20 per completed in-home study visit (Months 3, 6, 12 and 36) for expenses related to your participation. If you are unable to complete the in-home study visit, $10 will be reimbursed to you for each completed phone interview. If you decide to not participate in this study, your doctors will continue to treat you according to their usual treatment plan.

• You may receive a direct benefit for participating in this research study. If the evaluations on your blood and urine show evidence of CKD, a referral will be sent to your PCP recommending follow up medical evaluation.

• You and your insurer or third party payer will not be billed for research-related services. All research related testing and procedures will be paid for by the research study. 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 such as, if you are admitted into the hospital or go for outpatient testing separate from this research study.

• If you believe that the research procedures have resulted in an injury to you, immediately contact the **Principal Investigator, Dr. Katrina Hawkins**, 202-715-4543 who is listed on the first page of this form.

By signing this form you authorize the Study Doctor and members of the research team to use and share with others (disclose) your protected health information (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.

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

This consent form;

Your name, date of birth, social security number and/or medical record number;

Your address and telephone number for the purpose of follow-up.

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.

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

- 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 ProGReSS AKI and ConsequenceS Coordinating Center and required federal agencies that are providing oversight including the NIH/NIDDK, who is sponsoring this study and any contractors or partners they may have (including research monitors, auditors, and the study's Data Safety Monitoring Board);
- The University of Pittsburgh Research Conduct and Compliance office may have access to Identifiable records for purposes of monitoring the conduct of the study;
- The CRISMA Molecular Core Laboratory that will receive your blood and urine;
- Hooper Holmes, Inc. (HHI) A paramedical examiner employed by HHI will have access to research data/documents because they will be performing the home visits;
- 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;

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.

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 Katrina Hawkins, 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 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.

If the investigators feel that you cannot complete the study requirements, they may withdraw you from the study.

VOLUNTARY CONSENT

The study has been described to you and all of your questions have been answered. Any additional questions or concerns about any aspect of this study will be answered by the researchers. 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.

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

_____ _____ _____

Name of Participant (print) Signature of Participant Date

SURROGATE CONSENT

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

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

_____ _____ _____

Legally Authorized Representative (print) LAR Signature Date

LAR relationship to Participant: _____

_____ _____

Witness Signature Date
(if faxing or Electronic transfer)

Certification of Informed Consent

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/surrogate and any questions about this information have been answered.

_____ _____ _____

Person obtaining consent (print) Signature of person obtaining consent Date