

Research Consent Form

Protocol to Assess the Severity of Acute Kidney Injury

(PASS KI Study)

GW IRB Reference number: IRB #010835
Principal Investigator or Study Doctor: Lakhmir Chawla, MD
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Sponsor: The Department of Anesthesiology and
Critical Care Medicine

1) **INTRODUCTION**

You are invited to participate in a research study. Before you decide to be a part of this study, you need to understand the risks and benefits. This consent form provides information about the research study. A staff member of the research study will be available to answer your questions and provide further explanations. If you agree to take part in the research study, you will be asked to sign this consent form. This process is known as informed consent. Your decision to take part in the study 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 Hospital (GWUH). You 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.

This study is being conducted by the investigators listed above from the Department of Anesthesiology and Critical Care Medicine of the George Washington University Medical Faculty Associates (GWU MFA). The costs of this research study are paid for by the Department.

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?**

The Department of Anesthesiology and Critical Care Medicine of the GWU MFA is carrying out this research study to find out new indicators to tell us which patients are at higher risk for Acute Kidney Injury (AKI) early in the course of the disease. Currently, there is no effective treatment for AKI.

The kidney is an organ in your body that cleans the blood by filtering out the waste products. This waste is then converted into urine. A person has AKI when his or her kidneys are not working properly. Currently, doctors detect AKI by checking both urine output and the amount of waste in the blood.

We are trying to find out if the urine produced by your body is a good indicator of the course that the disease may take during your stay in the hospital. This would enable doctors to predict the severity of Acute Kidney Injury earlier and start treatment immediately to prevent further injury or help the kidney recover from the damage that may have already taken place.

You are invited to participate in this study because you are at high risk of kidney injury (this is based on your admission to the intensive care unit and/or your underlying disease condition). We will monitor your urine output for a maximum of 14 days or until you are discharged, if sooner than 14 days. There is no post-discharge follow-up.

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

You will be one of approximately 150 participants to be asked to take part in this study. All study participants will be patients of the GWU Hospital. Activities related to this study will take place at the GWUH.

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

If you choose to take part in this study, this is what will happen:

- We will take your health history and examine you;
- A single dose of furosemide will be given to you. If you used furosemide before being admitted to the hospital, you will receive a dose of 1.5 mg/kg weight. If you did not use furosemide before, then you will receive only a dose of 1.0 mg/kg. After the furosemide is administered, we will measure how much urine you produce after 6 hours.
- We will collect two blood samples of 7 milliliters (one and a half teaspoon) in the first day of enrollment, and then another during the next 24 hours. Blood samples will be drawn by putting a needle into your vein or from a catheter that is in your vein already.

- We will also collect your urine. We will collect 2 samples of urine. Each sample will be 50 cc (10 teaspoons) and will be collected in the first and second day of the study.
- You will be in the study for a maximum of 14 days or until you are discharged, if sooner than 14 days. No further interventions will be administered to you during this period. During this period, we will record the clinical and laboratory results and monitor you for development of acute kidney injury.
- If you are a woman of reproductive age, we will take a urine pregnancy test. If you are pregnant, you cannot take part in this study.

The total amount of time you will spend in connection with this study is 14 days or until you are discharged from the hospital – whichever comes first. 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.

5) WHAT ARE THE RISKS OF PARTICIPATING IN THIS STUDY?

During this study, you will be given a single dose of furosemide (lasix). Furosemide is the standard treatment used in the hospital to increase the urine output of patients. Though furosemide has a very good safety profile, it may have some risks. You may experience allergic reactions or damage to your hearing. In addition, you may lose fluids, electrolytes and minerals that may lead to dehydration. To avoid loss of body fluids, each milliliter of fluid lost will be replaced by the same amount of fluid through your IV. Since you are in the hospital, we will be watching your electrolyte and mineral levels each day to make sure that they are not depleted.

We will collect a total of two blood samples of 7 milliliters each (one and a half teaspoon) during the first day and the second of the study. Blood samples will be drawn by putting a needle into your vein or from a catheter. This is standard method used to obtain blood for tests. When blood samples are taken, there are possibilities of a bruise and slight pain. Rarely, fainting or infection may also occur. If you are in the ICU and have an intravenous catheter, most of the blood samples will be taken from the catheter so a needle stick will not be necessary.

We will also collect your urine. We will collect 2 samples of urine. Each sample will be 50 cc (10 teaspoons) and will be collected in the first and second day of study. There is no risk to you in urine collection.

Reproductive Risks

Furosemide does not influence your capability of getting pregnant or to fathering a baby. However, if you are a woman who is capable of becoming pregnant, we will ask you to have a pregnancy test before beginning this study. The pregnancy test will be provided without charge by the team conducting the study.

Results from Disease Specific Testing

The analyzing of blood and urine samples will continue for an extended period after your enrollment in the study. Generally, you will not be told the results of this study.

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

If you agree to take part in this study, there may not be direct medical benefit to you for participating in this study. However, you will receive an assessment of your kidney function that might not otherwise occur.

We hope the information learned from this study will benefit other individuals with potential acute kidney injury in the future or aid in our understanding of disease development and treatment.

7) **WHAT ARE MY OPTIONS?**

You do not have to take part in this study if you do not want to participate. The participation is completely voluntary. Should you decide to take part and later change your mind, you can do so at anytime without penalty. If you decide not to participate in this study, your doctor will continue to treat you according to the usual treatment plan.

You will be informed if any additional risks are found to be associated with participation in this study.

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

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

9) **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 charged for the following that are part of this research study:

- One single dose of Furosemide.
- Pregnancy test

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: 202-715-4110

10) ARE THE RESEARCHERS BEING PAID FOR THE STUDY?

The sponsor of this study, the Department of Anesthesiology and Critical Care Medicine, is paying the research team for their work in this study.

11) 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 from GWUH and/or the GWU MFA or through your physician or treatment center of choice. Care for such injuries will be billed in the ordinary manner to you or your insurance company. 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, GWUH and/or the GWU MFA for any injuries or illnesses. You do not waive any liability rights for personal injury by signing this form.

12) 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.

Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. 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.

13) 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, age, race, gender, height and weight;
- Your history of medical conditions including heart, liver 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;
- Laboratory results obtained on samples collected from you (like blood tests for cell counts such as white cells, red cells and platelets (hematology), creatinine, blood sugar and other minerals (chemistry), clotting tests (coagulation), blood oxygen (arterial blood gases) and urine tests for cultures and cell counts (urinalysis).

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 research team, and
- other healthcare providers such as labs which are part of the study.

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

- GWU Institutional Review Board (“IRB”) or its authorized representatives, as well as representatives of the Office for Human Research Protections (OHRP) who may review your records to ensure that your rights as a research subject are protected;
- GWU workforce and your health insurer to discuss payment or get paid for services that are not paid for by the research;
- 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 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 Dr. **LAKHMIR CHAWLA** of the GWU MFA stating that you are canceling your authorization. This letter must be signed and dated and sent to this address:

LAKHMIR CHAWLA
Anesthesiology and Critical Care Medicine
GEORGE WASHINGTON (GW) UNIVERSITY HOSPITAL
900 23-RD STREET, NW
WASHINGTON DC 20037

A copy of this revocation will be provided to the 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 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.

14) 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 furosemide, you may still be required to have certain follow-up tests and procedures to ensure your safety and health.

15) CAN I BE TAKEN OFF THE STUDY?

The study Doctor 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 study doctor may stop the study at any time.

16) 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 Dr.Lakhmir Chawla. His telephone number is 202-715-4570.

17) 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:

18) DOCUMENTATION OF CONSENT

Subject's Name (printed) Signature Date

Name (printed) and Signature of Authorized Representative Date

Relationship to Participant _____

Name (printed) and Signature of Person Obtaining Consent Date

Principal Investigator's Signature Date

DO NOT SIGN AFTER THE EXPIRATION DATE OF: 2/26/2012

