
MEDICAL FACULTY ASSOCIATES

THE GEORGE WASHINGTON UNIVERSITY

Research Consent Form

Search For Novel Methods to Detect Bowel Inflammation/Ischemia and Diagnose Acute Abdominal Complaints

GW IRB Reference number: 040704

Principal Investigator or Study Doctor: Lakhmir Chawla, M.D. (202) 715-4570

Sponsor: Department of Anesthesiology and Critical Care Medicine

1) INTRODUCTION

You are invited to participate in a research study of intestinal disease. You are being asked to take part in this research study because you either have abdominal pain/complaints that may be due to poor blood flow to or inflammation of your intestine, or you are serving as a control patient. Control patients are those undergoing elective surgery without intestinal disease, or those being admitted for pneumonia. 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 GWU Hospital. 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 Department of Anesthesiology and Critical Care Medicine: GWU Medical Faculty Associates (MFA). The costs of this research study are paid for by Department of Anesthesiology and Critical Care Medicine.

Before you decide to participate, please take as much time as you need 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?

The Department of Anesthesiology and Critical Care Medicine of The George Washington University Medical Center are carrying out a research study to find out if we can potentially detect certain bio-markers or proteins (building blocks of the body) that are different in patients with intestinal disease.

The intestine is an organ in your body that absorbs the food that you eat. When a person has inflammation of the intestine or intestinal ischemia (that means that the intestine is not getting enough oxygen) the intestine can break down. A person with intestinal ischemia can die if they do not get treatment. For example, patients with appendicitis have intestinal inflammation that can lead to a small area of intestinal ischemia which can lead to a leak of the intestine. Currently, doctors detect intestinal inflammation and ischemia by doing radiology tests (like an x-ray or CT scan). We are trying to find other substances in blood and urine that will let doctors know whether or not a person has intestinal inflammation or ischemia. We hope that we can find substances that show up early on in the injury. This would enable doctors to treat patients with new therapies that will prevent further injury or help the intestine recover from the damage that has already taken place.

3) HOW MANY PEOPLE WILL TAKE PART IN THE STUDY

About 300 participants at one institution will be asked to take part in this study. You will be one of approximately 300 participants to be asked to take part at this location.

4) WHAT IS INVOLVED IN THIS STUDY?

The Study Doctor or a member of his research team will review your medical and laboratory records to make sure you are eligible to participate.

If you choose to take part in this study, this is what will happen: After you sign the informed consent form, we will collect clinical (medical) data from your chart related to intestinal disease. We will then draw one teaspoon of blood and one tablespoon of urine.

The clinical data, blood and urine samples collected during this study are important to this study and to future research. If you join this study, George Washington University or its outside partners in this research will own this data and blood and urine samples. The data and blood and urine samples will be coded to protect your identity and sent to a laboratory at the National Institutes of Health. This material will be studied, tested, and used by medical scientists. If this material helps lead to the creation of a product or idea, whoever creates that product or idea will own it. You will not receive any financial benefit from the creation, development, use or sale of that product or idea.

Dr. Lakhmir Chawla, the study's Principal Investigator, may choose to withdraw you from this research study at any time.

5) HOW LONG WILL I BE IN THIS STUDY?

The total amount of time you will spend in connection with this study is just the time that you are in the hospital.

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?

For the blood sample drawn, approximately one (1) teaspoon of blood will be removed. Blood samples will be taken by putting a needle into your vein. 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. The total amount of blood that we would draw is approximately 1 teaspoon.

For the urine sample, approximately one (1) tablespoon of urine will be removed. Urine sample will be taken from a urinary catheter if there is one in place or you will be asked to provide urine in a specimen cup. There are no side effects of obtaining a urine sample as your body is eliminating the urine. The total amount of urine that we collect is approximately 1 tablespoon.

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

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

8) WHAT ARE MY OPTIONS?

You do not have to take part in this study if you do not want to participate. Should you decide to take part and later change your mind, you can do so at anytime.

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.

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: 202-715-4500.

11) ARE THE RESEARCHERS BEING PAID FOR THE STUDY?

The sponsor of the study is not paying George Washington University and the Study Doctor and his/her 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 from GWU Hospital 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, 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?

All information that is collected will be stored in a locked office. No unauthorized personnel will be allowed to view your personal information.

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.

14) HOW WILL MY PRIVACY BE PROTECTED?

All information that is collected will be stored in a locked office. No unauthorized personnel will be allowed to view your personal information.

Federal law requires 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;
- Information about your medical history related to intestinal disease or your admitting diagnosis (control group) from your medical records and your doctor's office;
- Information obtained from you to be used in the Study as a result of tests (such as a CT scan) or procedures (such as surgery) related to intestinal disease or your admitting diagnosis (control group);
- Blood and urine samples collected from you to identify biomarkers of intestinal disease or your admitting diagnosis (control group).

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.

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 of Human Research Protections (OHRP) who may review your records to ensure that your rights as a research subject are protected;
- Accrediting agencies and legal counsel

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 of the Principal Investigator, Lakhmir S. Chawla, MD stating that you are canceling your authorization. This letter must be signed and dated and sent to: 900 23rd street, NW, #G-105, Washington DC, 20037, 202-715-4570. 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 [investigational drug or device], 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.

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:

DOCUMENTATION OF CONSENT

_____	_____
Subject's Name (printed) and Signature	Date and Time
_____	_____
Name (printed) and Signature of Person Obtaining Consent	Date
_____	_____
Principal Investigator's Signature	Date

DO NOT SIGN AFTER THE EXPIRATION DATE OF: 08/31/2010

