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: Danielle Davison, M.D. (202) 715-4089

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 (such as hernia repair), or those being treated for pneumonia or upper respiratory infection (URI). Your participation is entirely voluntary.

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 purpose of this research study to find out if we can detect certain bio-markers or proteins (building blocks of the body) in the blood and urine 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,

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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

You will be one of approximately 400 participants to be asked to take part in this study.

4) WHAT IS INVOLVED IN THIS STUDY?

The Study Doctor or a member of her 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 three teaspoons of blood and two tablespoons of urine (if urine is available). These samples will then be sent to a lab for bio-marker analysis and identification as described in section 2 above. You will not be informed about the results of the blood and urine analysis.

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. Your study participation is completed on the day of enrollment.

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

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 urine sample will be taken from a urinary catheter if there is one in place or you may 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.

There is the possible risk of a breach of patient confidentiality that will be minimized to the extent possible. Specifically, your personal identifiers will be removed from study data and samples and will be replaced with a four digit subject number. The code linking your subject number to your study data and samples will be securely stored in the locked department research office. Only the study team will have access to the code.

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

There will not be any direct benefit to you by taking part in this study; however, we hope that by findings bio-markers, we will be able to help other people with intestinal inflammation or ischemia in the future.

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.

10) 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. If you join this study, the blood and urine samples collected may be shared with other labs that will be responsible for doing the testing. The samples may also include data, such as your age, and gender. When this information is sent, the data, blood and urine samples will be coded to protect your identity. This means that only members of the research team will know your identity and be able to link your identity with your sample or data.

Once the lab testing is complete, the samples and data will be retained for a maximum of five years and will then be destroyed. There are no plans to conduct any future research with the samples or data that you provide.

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.

11) 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

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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.

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. However, if you do not give permission to use your PHI, you may not take part in this study because your PHI is needed in order to conduct this study" to the Confidentiality section of the Research Consent form.

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 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 diagnosis (control group);
- Blood and urine samples collected from you to identify bio-markers of intestinal disease or your 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, may review your records to ensure that your rights as a research subject are protected;
- Laboratories who are performing the testing for the study; and
- 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

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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, Danielle Davison, 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.

12) 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.

13) 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.

14) 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. Her telephone number is 202-715-4089

15) 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)	Date	**Time**

_____

Subject's Signature

_____	_____
Name of Person Obtaining Consent (printed)	Date

_____

Signature of Person Obtaining Consent

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