

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Study to Identify and Validate Novel Biomarkers from Cardiovascular Surgery Patients at Risk for Acute Kidney Injury

PROTOCOL NO.: AST-107LC
WIRB® Protocol #20090471

SPONSOR: Astute Medical, Inc.
San Diego, California
United States

INVESTIGATOR: Danielle Davison, M.D.
#G-105
900 23rd Street Northwest
Washington, District of Columbia 20037
United States

SITE(S): George Washington University Hospital
#G-105
900 23rd Street Northwest
Washington, District of Columbia 20037
United States

**STUDY-RELATED
PHONE NUMBER(S):** Danielle Davison, M.D.
202-715-4089
202-494-8600 (24 hours)

In this consent form, “you” always refers to the subject. If you are a legally authorized representative, please remember that “you” refers to the study subject.

General Information

You are being asked to participate in this clinical research study because you are scheduled to undergo heart surgery and may be at risk for kidney injury. Before agreeing to participate in this research study, it is important that you read this consent form. It describes the purpose, procedures, benefits, foreseeable risks and discomforts of this study. You should take part in the study only if you want to do so. If this consent form contains any words or statements that you do not understand, please ask your study doctor or a member of the study staff to explain them. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Please tell the study doctor or study staff if you are currently taking part in another research study.

In the event that you are not able to give consent to participate in this study due to your condition, the word “you” refers to your Legally Authorized Representative (LAR) who will be signing this consent form on your behalf.

If you are the legal representative of a person who cannot consent for themselves at this time, you should know that the study staff will discuss the study with the person if they become alert at any time during the study period. They will be informed of who signed this consent form and that they have a right to withdrawal.

Source of Funding

This study is being funded by Astute Medical, Inc. Astute Medical, Inc. will pay your study doctor or the institution to cover costs related to perform this research.

Purpose of Study

The purpose of this study is to look for new biomarkers in blood and urine that might be related to kidney damage caused by heart surgery. Biomarkers are substances that are found in blood or tissue that may be used to indicate or measure the effects or progress of a disease, illness or condition.

Approximately 600 subjects undergoing heart surgery and might be at risk for kidney injury are expected to enroll in this study.

Study Visits and Procedures

Screening

If you agree to take part in this study, you will be asked to sign this consent form and a member of the study staff will review your medical history (including your laboratory test results and medications). This information will be used to determine if you are eligible to take part in the study.

If you are enrolled, the length of your participation will be 7 days after your heart surgery or while you are in the hospital if your stay in the hospital is less than 7 days.

Baseline (Before your Heart Surgery)

If you qualify for the study and are enrolled, the study staff will collect information and laboratory tests related to your baseline kidney function from the previous five days. These laboratory tests would have been taken as part of your routine care.

Within 3 hours of your heart surgery, about 1 ½ tablespoons of blood and about 2 ½ tablespoons of urine will be collected as part of this study.

Study Period (Up to 7 days after your Heart Surgery)

For up to seven days, while you are in the hospital, results from laboratory tests and information about your heart surgery, kidney function, and medical status will be collected as part of this study. Additional blood and urine samples will be collected (about 1 ½ tablespoon blood and 2 ½ tablespoons of urine each) at the following times while you are in the hospital:

- enrollment;
- 3 hours after surgery;
- 6 hours after surgery;
- 12 hours after surgery;
- 24 hours after surgery;
- 48 hours after surgery;
- and once each day on days 3, 4, 5, 6 and 7 after your surgery, if you are still in the hospital on these days.

Follow-up (Up to 30 days after your Heart Surgery)

For up to thirty days after your heart surgery, the study staff will collect the results from additional laboratory tests taken as part of your routine care and information related to your kidney function and medical status. This information will be taken directly from your medical records.

The study staff may try to contact you or a family member/caregiver around 30 days after your heart surgery to check on your health status. If you have returned to the hospital after your discharge and within 30 days of your heart surgery, the study staff may review your medical record for information about your additional hospital stay.

Study Blood and Urine Samples

A total of about 9 ½ tablespoons of blood and about 1 ½ cups of urine will be collected for this study. At each sampling time described above, about 1 ½ tablespoons of your blood and about 2 ½ tablespoons of your urine will be collected. The blood and urine samples will be processed at the clinical site, frozen and shipped to Astute Medical, Inc. or a designated laboratory for analysis (tests). The results of this testing will not be available to any of the Emergency Department, hospital or clinical study staff during the study and therefore will not impact your care.

Any remaining blood or urine samples along with the anonymized information described above will be stored at Astute Medical, Inc. in San Diego, California and may be used for future analysis of markers for kidney damage and other diseases. The specimens and information may be kept for a prolonged period (possibly 25 years or longer). The samples will NOT be submitted to a cell/DNA (the chemical that makes up genes) bank and will NOT be used for genetic testing.

All samples and information from each subject in this study will be identified by an anonymized barcode number and will not be otherwise individually identifiable.

Subject Responsibilities and Withdrawal Information

As a subject in this study, you will be asked to complete all visits and procedures as described above. If you wish to withdraw from the study, you should contact your study doctor or study staff.

The study doctor will still be able to use the information about you that was collected before your withdrawal from the study. Information already provided to the study sponsor cannot be withdrawn.

Potential Risks and/or Discomforts

Blood samples will be collected during this study. These will be obtained in one of two ways: (1) a needle will be inserted into a vein in your arm and small samples of blood will be taken, or (2) small samples of blood will be taken from an existing catheter (thin hollow plastic tube placed into a vein in your arm). Collecting blood samples may cause fainting, and/or some pain and/or bruising at the site on your arm where your blood was taken. On rare occasions, infection may occur. You will be carefully observed for these and any other symptoms. Appropriate medical care will be given if they occur.

There are no known risks to providing a urine sample.

New Findings

You will be told about any new information that might change your decision to be in this study. You may be asked to sign a revised consent form if this occurs.

Potential Benefits

This is not a treatment study. You will not directly benefit from the study. Future patients may benefit from the research conducted on the samples collected as part of this study.

Costs for Participation

You will not have to pay for any of the study tests. However, while you are in the study, you still need to get regular medical care. You (and/or your healthcare payer) will still have to pay for the costs of your regular medical care that are not a part of this study.

Payment for Participation

There will be no payment to you for participation in this study.

Commercial Issues

The sponsor has no plans to pay you for discoveries or commercial products that might result from this study or from the samples collected in this study.

Alternative to Being in the Study

This is not a treatment study. Your alternative is to not be in the study.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

Access to your study records will be limited to those who need the information for purposes of this study, as well as your health care providers if they need access to the information. All records will be kept in a secure location and access will be 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.

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;
- Demographic information (like your name, address, date of birth, social security number, etc.);
- Information about your medical history from your medical records and your doctor’s office;
- Information obtained from you to be used in the Study as a result of tests or procedures;
- Results of physical examinations
- Laboratory results obtained on specimens collected from you (like blood, urine, tissue);
- Medical images like x-rays, CT scans, and MRIs;
- Admissions information;
- Health care expenses and health insurance coverage information;
- Interviews with you conducted by members of the Research Team; or
- Other data created or collected during this study.

By signing this form, you allow the use, sharing, copying, and release of your protected health information to carry out the study by:

- Your healthcare providers (like doctors and hospitals) which are not part of the study,
- The study doctor and his or her research team, and
- Other healthcare providers such as labs which are part of the study.

You also allow the study doctor and the research team, and other healthcare providers which are part of the study 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;
- Western Institutional Review Board (WIRB);
- The sponsor of the study and any contractors or partners it may have (research monitors and auditors);
- Research collaborators participating in this multi-site study at other institutions (Data receiving center(s) responsible for collecting, monitoring and /or analyzing data from all the sites participating in this study);
- 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;
- Representatives of foreign governments who are responsible for approving the sale of medical products in their country (similar to the U.S. FDA) for the purpose of reviewing data about the safety and effectiveness of the product tested in this study;
- Accrediting agencies and GWU legal counsel;
- 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. Such cancellation will not affect information a healthcare provider has already used in reliance on your permission to do so. 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 your study doctor. This letter must be signed and dated and sent to this address: Danielle Davison, M.D. at #G-105, 900 23rd Street Northwest, Washington, District of Columbia 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.

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.

Injury Compensation

You may have medical problems or side effects from taking part in this research study. If you believe that you have been injured or have become ill from taking part in this study, you should seek medical treatment right away. This can be done through:

- GWU Hospital and/or the GWU MFA or
- your physician or
- treatment center of your choice.

You or your insurance company will be billed for this care. Your insurance company may not pay for such care because you are participating in a research study. You should contact the study doctor as soon as possible about any research related illness or injury.

There are no plans for GWU, GWU Hospital and/or the GWU MFA to pay you for any injuries or illnesses. By signing this form you will not give up any legal rights.

Voluntary Participation/Withdrawal

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

In addition, the study staff, Astute Medical, Inc. or the institution may stop you from taking part in this study at any time without your consent:

- if it is in your best interest;
- if you do not follow the study rules;
- if the study is stopped;
- you do not later consent to any future changes that may be made in the study plan;
- or for any other reason.

Whom to Contact to Ask Questions About Your Rights as a Research Subject

If you have any questions, concerns or complaints about the study, your participation in the study or if at any time you feel you have had a research-related injury, please contact Dr. Danielle Davison or the study staff at 202-715-4089 during regular business hours and at 202-494-8600 after hours (24 hours).

If you have questions about your research rights or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789 or 360-252-2500
Email: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to be in this study, you will be given a copy of this signed and dated consent form.

Subject's Consent to Participate

I have read the above information (or it has been read to me), I have been given the opportunity to ask questions, and my questions have been answered to my satisfaction. By signing this consent form, I voluntarily consent to participate in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

Consent and Assent Instructions:

Consent: Subjects able to provide consent must sign on the subject line below.

Consent is provided by the Legally Authorized Representative for subjects unable to consent.

Assent: Is required for subjects able to provide assent.

Subject's Name (Please Print) (if no Legally Authorized Representative is used)	Subject's Signature	Date
--	----------------------------	-------------

OR

Legally Authorized Representative's Name (Please Print)	Legally Authorized Representative's Signature	Date
--	--	-------------

Authority of Subject's Legally Authorized Representative or Relationship to Subject

Name of Person Conducting Informed Consent Discussion (Please Print)	Signature of Person Conducting Informed Consent Discussion	Date
---	---	-------------

ASSENT SIGNATURES, For Subjects with a Legally Authorized Representative:

Assent:

For subjects who have a legally authorized representative, I confirm that:

I have explained the study to the extent compatible with the subject's understanding, and the subject has agreed to be in the study.

OR

The subject is not able to assent due to lack of mental capacity.

Signature of Person Conducting Assent Discussion

Date

----- Use the following only if applicable -----

If this consent form is read to the subject because the subject (or legally authorized representative) is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject (or the subject's legally authorized representative). The subject (or the subject's legally authorized representative) freely consented to be in the research study.

Impartial Witness
(Print Name)

Signature of Impartial
Witness

Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.