Subject Name: _____ Date: _____

Title of Study: **Investigation of Advanced Imaging Modalities in Humans, #06-084**

Principal Investigator: Edward H. Livingston, M.D.

Co-Investigator(s): Sergio Huerta, M. D.

Study Coordinators: **Karel J. Zuzak, Ph. D.; Sabira Naik; Tinsy Perumanoor; Santosh Hariharan; Renae Arbabian; Augustus J. Rush**

Before agreeing to take part in this research study, it is important that you read and understand the following explanation of the proposed procedures. It describes the procedures, benefits, risks and discomforts of the study. It also describes alternative treatments that are available to you and your right to withdraw from the study at any time. It is important for you to understand that no guarantees or assurances can be made about the results of the study.

1. WHAT IS THIS RESEARCH STUDY ABOUT?

You are being asked to participate in this research project to determine if a new imaging technology will provide useful information regarding blood flow and blood containing structures. Because of your current medical condition, your participation may help refine this technology for the benefit of future patients with the same or similar conditions.

Because you are electing to undergo a surgical procedure for the management of your current medical condition, you may be eligible to participate in this study. The expected number of participants is this pilot study is 50. This pilot study is designed to determine the feasibility of use of this new imaging technology. Once we have established the feasibility of our study and have the appropriate protocols and facilities at the Dallas VA, we will enroll more patients to a number that will allow us to determine if we can use the imaging technology for the benefit of patients with the same or similar medical conditions..

2. WHAT WILL HAPPEN DURING THE STUDY?

If you agree to participate in this study, one of the researchers will ask you about your age, and about your overall health prior to surgery. Once you are enrolled in the study, you will be prepared for you operation in the usual routine. Prior to or during your operation, as long as it doesn't interfere with the conduct of your operation, the imaging device will be used to capture several images (approximately 2-3 minutes) of the structures of interest. The images will not be shared with the physicians conducting your operation or deciding your care while in the

SUBJECTS IDENTIFICATION (I.D., plate or give name-last, first, middle)

hospital.

3. WHAT ARE MY RISKS?

Because this imaging technology does not require an invasive procedure or insertion of needles , it is a very safe and painless procedure.

Unforeseen risks: A previously unknown problem could result from your taking part in this research. It is not possible to estimate the chances of such problems or how serious problems could be. Any new findings will be given to you that may affect your willingness to participate in this study. If new findings are discovered, you will be asked to sign a new (updated) informed consent form to document that this new information has been explained to you.

4. WILL THE RESEARCH BENEFIT ME OR OTHERS?

This specific research project will not be of direct benefit to you.

This study will benefit others as we learn more about the camera and the information that it gives us. In the future we may be able to use this device to better understand how blood flow affects certain disease processes, improving our ability to treat them.

5. WHAT ARE MY ALTERNATIVES TO BEING A RESEARCH SUBJECT?

You may choose either to participate or not to participate in this research. Whatever your decision, your medical care at the Dallas VA Medical Center will be independent of your participation in this study.

6. WILL I GET PAID?

You will not be paid for your participation in this study.

7. WILL I HAVE TO PAY?

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You will not have to pay for your participation in this study. Subjects do not pay for treatment associated with participation in a VA research program.

8. DOES BEING PREGNANT OR THE POSSIBILITY OF BEING PREGNANT PREVENT ME FROM TAKING PART?

Every effort will be made to have women enter this study on an equal basis with men. You should know that it is very important for your surgeon to know if you are pregnant before he/she operates on you. The surgery, anesthesia, and medicinal management of your particular illness can have adverse affects on you and your baby.

9. WHAT IF I GET INJURED?

You do not give up any legal rights to payment for injuries caused by research by signing this form. The Federal Tort Claims Act is a way to request compensation from the government for injuries related to research in VA research subjects. Investigators at the VA will advise you about medical treatment available at the Dallas VA Medical Center in case of bad effects, which you should report to them promptly. Investigator's phone numbers are listed at the end of this form.

10. ARE MY RESEARCH RECORDS SAFE FROM THE PUBLIC?

The investigators maintain confidentiality of your research records in the same way as your other medical records. No one has access to your records except as required by law. You are, however, authorizing the Dallas VA Institutional Review Board (IRB), the Dallas VA Research and Development Committee and the members of the Dallas VA Research Office to inspect your medical and research records. These committees, people, and offices at the Dallas VAMC are responsible for overseeing human research studies.

By signing this form, you will allow the Veterans Health Administration (VHA) to provide Dr. Livingston and his research team access to the following health data about you:

1. Information contained in the electronic medical record (CPRS) such as medical history, surgical procedures, medications, and pathology results.
2. Use of your tissue for cell culture experiments.

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If you do not sign this authorization you will not be part of the study.

This approval to use your health information has no expiration date.

The VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and all other laws that protect your privacy. We will protect your health data according to these laws. Despite these protections, there is a possibility that your health data could be used or disclosed in a way that it will no longer be protected. Our Notice of Privacy Practices (a separate document) provides more information on how we protect your health data. If you do not have a copy of the Notice, the research team will provide one to you.

If you choose to take part in the study, certain government agencies (such as the FDA or VA) may look at your research records. Your name as a subject in this study is private, and will not be included in any publication prepared as a result of this study.

11. DO I HAVE TO TAKE PART IN THIS STUDY, OR CAN I WITHDRAW FROM THE STUDY?

Participation in this study is voluntary and you may refuse to take part without penalty or loss of benefits to which you are otherwise entitled. You are free to withdraw your consent and stop taking part at any time. Discontinuation will in no way affect or jeopardize the quality of care you receive now or in the future from the VA. This will also not affect your right to take part in other studies. The investigators will answer any questions you may have about the study.

You can also take back your authorization for the VHA or the study doctors to access or to share your health data with outside parties at any time. To stop taking part in the study or to take back your authorization, you should contact both:

1) **Dr. Livingston or his representative listed at the bottom of this form, and**
2) **the IRB Administrator of the Dallas VA Medical Center [telephone: 214-857-0291; mail: Dallas VA Medical Center, IRB Administrator (151)**

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4500 S. Lancaster Rd.
Dallas, TX 75216).

If you decide to take back your authorization, you will be given a form to show your desire in writing. If you take back your authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient.

If you take back your authorization, Dr. Livingston and his research team can continue to use information about you that has been collected. No health data will be collected after you take back the authorization.

Your doctor may also take you out of the study without your consent for medical or administrative reasons. Any significant new findings that develop during the course of the research study that in the opinion of the investigator may affect your willingness to continue to participate, will be given to you as soon as possible.

12. WHOM SHOULD I CONTACT FOR QUESTIONS OR PROBLEMS?

If you have any questions regarding this study or have an unexpected reaction to your treatment, you should call the study doctor, whose name and contact number appear on the last page of this form.

If you have any questions about your rights as a patient, complaints about your treatment or general concerns about the conduct of the research study, you may contact the **Dallas VAMC** Patient Representatives at 214-857-0482. The Patient Representative will guide you in resolving your question or complaint.

If you have a medical emergency you should immediately call 911 for assistance.

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If you would like to discontinue your participation in the study or to take back your authorization for the use of your health information, you should contact both:

1) **Dr. Livingston or his representative listed at the bottom of this form, and**
2) **The IRB Adminstrator of the Dallas VA Medical Center Center [telephone: 214-857-0291; mail: Dallas VA Medical Center, IRB Administrator (151) 4500 S. Lancaster Rd. Dallas, TX 75216)].**

3) **RESEARCH SUBJECT'S RIGHTS:**

I have read or have had read to me all of the above. The study has been explained to me and all of my questions have been answered. If I have questions later, I understand I can contact Dr. Livingston. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I understand that I do not have to take part in this study and my refusal to take part will involve no penalty or loss of rights to which I am entitled. I may withdraw at any time without penalty or loss of VA or other benefits to which I am entitled. The study physician can stop my participation at any time if it appears to be medically harmful to me, if I fail to follow directions for taking part in this study, if it is discovered that I do not meet the study requirements, or if the study is canceled.

In case there are medical problems or questions, I have been told I can call Dr. Livingston at 214-857-1800 during the day or at 800-725-4436 after hours.

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I understand my rights as a research subject, and I voluntarily consent to take part in this study. I understand what the study is about and how and why it is being done. I authorize the use of my identifiable patient health information as described in this form. I will receive a signed copy of this consent form.

Subject's Signature **Date**

Signature of Subject's Representative* and Date **Subject's Representative (print)**

***Only required if subject not competent.**

Signature of Witness and Date **Witness (print)**

***Only required if subject not competent.**

I certify that I have reviewed the contents of this form with the person signing above, who, in my opinion, understood the explanation. I have explained the known side effects and benefits of the research.

Principal Investigator or designee (Signature) **Date**

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Research Subject's Bill of Rights

1. Be informed of the nature and purpose of the research.

2. Be clearly told of the procedures to be followed in the medical research, and any drug or device to be used.

3. Be clearly told of any discomforts and risks that might be expected from the research.

4. Be clearly told of any benefits that the patient might expect from the research.

5. Be clearly told of any other appropriate procedures, drugs, or devices that might be helpful to the patient, and their risks and benefits.

6. Be clearly told how to get medical treatment, if needed, after the research is finished if problems should arise.

7. Be given the chance to ask any questions about the research or the procedures involved.

8. Be clearly told that consent to take part in the medical research and/or release of identifiable patient health information may be taken back at any time. The patient may stop taking part in the medical research without any penalty or loss of VA or other benefits.

9. Be given a copy of the signed and dated written consent form.

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10. Be given the chance to decide to consent or not to consent to a medical research study without any force, fraud, deceit, duress, coercion, or undue influence on the patient's decision.