UNIVERSITY OF CINCINNATI - Medical
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Improved Assessment of Coronary Flow Dysfunction using Fundamental Fluid Dynamics

UC IRB Study #: 10-05-05-02,2013-1256 **Sponsor Name:** Veteran Affairs Medical Center

Investigator Information:

Dr. Rupak K. Banerjee	513-556-2124	513-861-3100(Operator)
Principal Investigator Name	Telephone Number	24 hr Emergency Contact
Dr. Mohamed Effat	1-866-480-1734	
Co-Investigator Name	Telephone Number	24 hr Emergency Contact

Subject Name: _____ Date of Birth: _____/_____/____

INTRODUCTION:

Before you agree to participate in this research study, it is important that you be told the purpose, procedures, benefits, risks, discomforts and precautions of the research. You should also be told what alternative procedures are available to you if you do not participate in the research study.

Your participation in this research study is entirely voluntary. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without unfairness to you or your medical care. The study doctor(s) do not promise that you will receive any benefits from this study.

This informed consent document is a brief written summary of what your study doctor is telling you. Be sure to ask questions while you read this if there is anything that is not clear.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research study is to help doctors tell the difference between two heart conditions, one that causes diseases of larger blood vessels in the heart, and one that causes disease of small blood vessel in the heart. There are presently no tests that can tell us if you have disease in the small blood vessels.

We will use results from the tests your doctor will collect that are performed as usual care for your condition, or from another improved diagnostic and investigational test called Positron

emission tomography (PET) test. We will assess this information to determine if you may have disease of the small heart blood vessels. This may help your doctors know which condition you have and how to treat your condition.

WHY HAVE YOU BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You are being asked to take part in this research study because you

- are 18 years of age or older,
- Your doctor determined that you should be tested for coronary artery disease.

HOW LONG WILL YOU BE IN THE RESEARCH STUDY?

You will be in the research study till the completion of your coronary angiogram or upto 12 months.

The researcher may decide to take you off this research study at any time, for example, if you do not meet the inclusion or meet the exclusion criteria, or if the equipment used does not collect the information needed.

You may withdraw from the study at any time. If you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first so that stopping can be done safely. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful to you.

You will be contacted in the future by representatives of the VA and the University of Cincinnati who are interested in asking you follow-up questions and survey questions about your participation in this research study.

WHO IS CONDUCTING THE RESEARCH STUDY?

This study is sponsored by Veteran Affairs Medical Center.

The study is directed by Dr. Rupak K. Banerjee, researcher at the Cincinnati Department of Veterans Affairs Medical Center and Department of Mechanical & Biomedical Engineering, University of Cincinnati and Drs. Mohamed Effat and Imran Arif, Interventional cardiologists and researchers at the University of Cincinnati Medical Center (UCMC) and Cincinnati Department of Veterans Affairs Medical Center.

HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?

About 80 people will take part in this study.

WHAT IS INVOLVED IN THE RESEARCH STUDY?

A member of the study staff will explain the study and answer any questions you may have. If you agree to be in the study, you will be asked to read and sign the consent form.

☐ You are being asked to consent for the Part A (explained below) of this study:

A. The consulting Cardiologist, using his/her discretion, based on your history and symptoms will refer you to a heart imaging procedure. Results for Electrocardiogram (ECG) and heart imaging procedures that were done as part of your care for your coronary artery disease will then be reviewed by the study doctors. You will only be included in the study if you have abnormal ECG and/or heart images.

If the results are abnormal, you will be referred for the cardiac catheterization lab where you will have a coronary angiogram performed as part of your standard of care treatment procedure.

For severe blockages: In addition, based on the Cardiologist's discretion, we might insert the wire with pressure and flow sensors (Combowire) to assess the severe blockages (> 70% diameter blockage as seen on the heart images), for research purposes. The insertion of the Combowire for the assessment of severe blockages may not be part of the standard of care.

The Cardiologist treats the severe blockages using a stent. The Combowire used in the study is of the same size of the standard of care guide wire which is used to navigate the balloon catheter for stenting procedure. Therefore, in the case of severe blockages we would insert a Combowire instead of a similar-sized guide wire to obtain measurements and to guide the balloon catheter. Considering the same diameter for both the Combowire and the regular guide wire, we anticipate that the additional risks involved for you are minimal to none.

☐ You are being asked to consent for Part B (explained below) of this study:

B. If the consulting Cardiologist, using his discretion based on your history and symptoms, decides to take the heart images using an advanced imaging method known as Positron Emission Tomography (PET), you will be asked for your informed consent. This new imaging procedure is not part of your standard care but has been proven to be a very accurate diagnostic tool for better diagnosis of the heart diseases and is being further investigated. It would be done at no extra cost to you.

For the PET scan procedure, you will be positioned on the examination table and injected with a radiotracer in your hand or arm. You will then be asked to rest quietly, avoiding movement and talking. You will then be moved into the PET/CT scanner and the imaging will begin. You will need to remain still during imaging. The PET scan takes about 15-30 minutes. After this scan, you would remain on the examination table for about an hour. Then, you will receive adenosine (a standard of

care pharmacologic agent). Immediately, another injection of radiotracer is given and another PET scan is done for 15-30 minutes.

After the PET scans you will have a coronary angiogram performed as part of your standard of care treatment procedure.

For severe blockages: In addition, based on the Cardiologist's discretion, we might insert the wire with pressure and flow sensors (Combowire) to assess the severe blockages (> 70% diameter blockage as seen on the heart images), for research purposes. The insertion of the Combowire for the assessment of severe blockages may not be part of the standard of care.

The Cardiologist treats the severe blockages as per standard of care (with or without using a stent). The Combowire used in the study is of the same size of the standard of care guide wire which is used to navigate the balloon catheter for stenting procedure. Therefore, in the case of severe blockages we would insert a Combowire instead of a similar-sized guide wire to obtain measurements and to guide the balloon catheter. Considering the same diameter for both the Combowire and the regular guide wire, we anticipate that the additional risks involved for you are minimal to none.

Information collected during the coronary angiogram will be reviewed as part of this research study to find out if we can detect disease of small blood vessel using these measurements.

WHAT ARE YOUR RESPONSIBILITIES IF YOU PARTICIPATE IN THIS STUDY?

You will be responsible for coming to the researcher's office or hospital throughout the treatment period.

You might be asked not to participate in any other conflicting clinical research studies taking another investigational medicine (study drug).

WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?

The risks involved in participating in this research study are only related to the PET scan and insertion of Combowire for the assessment of severe blockages. All other procedures are part of your standard of care and will be explained in a separate consent form.

You will be exposed to radiation during PET imaging. The radiation you are exposed during PET scanning (N-13 Ammonia) is equivalent to the radiation our body receives from natural back ground sources over a year.

Side effects from cardiac stress testing and adenosine infusion can include chest pain, shortness of breath, headache and nausea. It is possible, although very unlikely, to have an allergic reaction to the radioactive substance.

In addition, the insertion of Combowire into severe blockages might create an additional risk. However, considering the same diameter for both the Combowire and the regular guide wire, we anticipate that the additional risks involved are minimal to none.

There may be unknown or unforeseen risks associated with taking part in this study.

WHAT ARE THE RISKS OF STOPPING YOUR CURRENT TREATMENT?

The study does not change the current treatment for your condition. You should not stop or alter dosages of medication on your own. It is very important that you consult with your doctor before stopping any of your medications. By stopping medications that your doctor has prescribed for your heart disease puts you at risk for serious health problems such as a heart attack.

WHAT ARE THE REPRODUCTION RISKS?

Pregnant women are excluded from this study due to the radiation exposure.

ARE THERE BENEFITS TO TAKING PART IN THE RESEARCH STUDY?

If you agree to take part in this research study, there may not be a direct medical benefit to you. The investigators hope the information learned from this research study will benefit other patients with large and small vessel heart disease in the future.

WHAT OTHER CHOICES FOR CARE ARE THERE?

Since this study is for research purposes only you do not have to participate in this study. If you do not choose to participate in this study, you will continue to be treated per the standard of care for a patient having a cardiac catheterization procedure.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE AND CONFIDENTIAL?

Every effort will be made to maintain the confidentiality of your study records. The Department of Veterans Affairs and the UCMC, and any sponsoring company, Agents of the United States Food and Drug Administration will be allowed to inspect sections of your medical and research records related to this study. The data from the study may be published; however, you will not be identified by name. Your identity will remain confidential unless disclosure is required by law.

Destruction of all research records pertaining to this study will be in accordance with the Department of Veterans Affairs record retention schedule.

Personal health information collected may include, but is not limited to, your name, date of birth, address, medical history, and results of all tests and procedures done during this study that are part of your standard of care.

You may ask the study doctor to see and/or provide you with a copy of your personal health information related to the study. You may also ask the study doctor to correct any study related information about you that is incorrect and/or incomplete. However, you may have to wait until the end of the study to see your study records, so that the study can be organized properly.

If you cancel your permission after you have enrolled in the study, the study doctor and/or his/her staff will stop collecting new information, including your personal health information, about you. However, the information that has already been collected will be used to evaluate the study results. If you cancel your permission to share your personal health information, you will not be able to continue to participate in the study. This is because the study doctor and/or his/her staff would not be able to collect the information needed to evaluate and/or compare the study data.

AVAILABILITY OF INFORMATION

You will receive a copy of this signed and dated consent form.

You will be told about any new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

WHAT ARE YOUR COSTS TO BE IN THIS STUDY?

Part B of this study has a PET cardiac scan which will be paid through the research money. The cardiac catheterization in the Part A and Part B are standard of care procedures and you may be responsible for the payments as per the regular UCMC requirements.

WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?

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

WHAT COMPENSATION IS AVAILABLE IN CASE OF INJURY?

The Department of Veterans Affairs will provide necessary medical treatment to you as a research subject if you are injured by participation in this research project, at no cost to you. This requirement does not apply to treatment for injuries that result from non-compliance by you with study procedures. The Department of Veterans Affairs does not normally provide any other form of compensation for injury. You have not released this institution from liability for negligence.

In the event that you become ill or injured from participating in this research study, emergency medical care will be provided to you. The VAMC or the UCMC will decide on a case by case basis whether to reimburse you for your out of pocket health care expenses.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

You may choose either to take part or not to take part in this research study. If you decide to take part, you may decide to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you. The investigators will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

If you have questions about the study, you will have a chance to talk to one of the study staff or your regular doctor. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

Nothing in this consent form waives any legal rights you may have nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

If you have questions, concerns or complaints about this research study or to report a research-related injury, please contact the researcher *Dr. Rupak Banerjee* at *513-556-2124 or Dr.Effat at* 1-866-480-1734

Please call the University of Cincinnati Medical Institutional Review Board at 513-558-5259 (Monday – Friday 8 am to 5 pm) if you:

- Think the research has hurt you.
- Have general questions about giving consent or your rights as a research participant in this research study.
- Have questions, concerns, or complaints about the research.
- Cannot reach the research team or you want to talk to someone else.

To report complaints or concerns to an independent agency in an anonymous and confidential manner, please call the Research Compliance Hotline at 1-800-889-1547.

PRIMARY CARE PHYSICIAN NOTIFICATION

Please indicate below whether you want us to notify your primary care physician or your specialist of your participation in this study.

_____ Yes, I want the researcher to inform my primary care physician/specialist of my participation in this study.

_____ No, I do not want the researcher to inform my primary care physician/specialist of my participation in this study.

_____ I do not have a primary care physician/specialist.

_____ The researcher is my primary care physician/specialist.

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Dr.Rupak K. Banerjee	513-556-2124	513-861-3100(Operator)
Principal Investigator Name	Telephone Number	24 hr Emergency Contact
Dr. Mohamed Effat	1-866-480-1734	
Co-Investigator Name	Telephone Number	24 hr Emergency Contact

SIGNATURES

I have read or someone has read to me, this Informed Consent Document which describes the purpose and nature of this research. I have had time to review this information and have been encouraged to ask questions. I have received answers to my questions. If I do not participate or if I discontinue my participation, I will not lose any benefits. I will not lose any legal rights if I discontinue. My participation in this research is completely voluntary. I give my consent to participate in this study. I have received (or will receive) a copy of this signed and dated form for my records and future reference.

Participant Date

PERSON OBTAINING CONSENT
I have read this form to the participant and/or the subject has read this form. An explanation of the research was given and questions from the participant were solicited and answered to the participant's satisfaction. In my judgment, the participant has demonstrated comprehension of the information.

Signature and Title of Person Obtaining Consent and Identification of Role in the Study Date