Department of Veterans Affairs | VA RESEARCH CONSENT FORM

Subject Name: _____ Date _____

Title of Study: Pressure Assessment to Improve Outcomes after TAVR: a registry

Principal Investigator: Anthony Bavry VAMC: North Florida/South Georgia Veterans Health System

UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM

to Participate in Research

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

For PI Use:

Participant Social Security Number: _____

SSN should be written on this consent form by the research team prior to scanning into the VHA health record; if the subject does not have a VHA health record, this requirement is N/A.

2. What is the Title of this research study?

Pressure Assessment to Improve Outcomes after TAVR: a registry

3. Who can you call if you have questionsconcerns, or complaints about this research study?

Principal Investigator: Anthony Bavry M.D. 352-548-4726

Other research staff: Debra Robertson RN 352-548-7724

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4. Who is paying for this research study?

Study drug (eplerenone) will be paid by the North Florida Foundation for Research and Education for the duration of the study. No additional funding is required to intiate or complete this study.

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board **(IRB) office at (352) 273-9600** or the North Florida/South Georgia Veteran's Health System Research Service Office at (352) 548-6069.

a) In general, what is the purpose of the research, how long will you be involved?

You underwent a procedure called transcatheter aortic valve replacement (TAVR) at the Malcom Randall VA Medical Center. As part of clinical care, the pressures inside your heart were recorded during that procedure and found to be abnormal. The abnormal pressures could be due to inability of the pumping chamber of your heart to relax normally.

The purpose of this research is to collect preliminary data to hopefully conduct a larger study on the use of a high blood pressure medication (eplerenone) in patients like you. Eplerenone was selected because research has shown that this medication, unlike other blood pressure medications, can help the heart to relax better.

b) What is involved with your participation, and what are the procedures to be followed in the research?

You will take eplerenone once daily for 8 weeks. You will also complete a quality of life questionnaire at the beginning of the study and again at 8 weeks.

c) What are the likely risks or discomforts to you?

Eplerenone can cause an elevation in an electrolyte in the blood called potassium. If potassium becomes severely elevated, life threatening heart rhythms can occur. Your potassium will be monitored by routine blood tests.

d) What are the likely benefits to you or to others from the research?

You might not directly benefit from this study; however, we are ultimately trying to improve outcomes for certain patients with high blood pressue and abnormal heart pressures after TAVR through use of the medication eplerenone.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

Continue current treatment for high blood pressure with any adjustments considered necessary by your doctor.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?

You will continue to be treated by your primary care provider and/or cardiologist for chronic medical conditions like high blood pressure.

7. What will be done only because you are in this research study?

You are potentially eligible because you underwent a TAVR procedure and the pressures in your heart were recorded. To determine if you are fully eligible, we will see if you have a diagnosis of high blood pressure, are taking blood pressure medications, or your systolic blood pressurehas been ≥130 mm Hg. We will also see if you had a recent blood draw, and if not, you will need to have one performed to evaluate your kidney function and potassium level. If you are a diabetic, you will need to have a urinalysis performed. Although eplerenone is a blood pressure medication, we do not expect large changes to occur to your blood pressure during

the study. Similary to when you start a blood pressure medication as part of routine clinical care, you may choose to check your own blood pressure. If you are concerned about a blood pressure reading, you can inform us or your provider for guidance. We will ask that you have a blood pressure performed in our research office (if you are local) or by your provider (if you are non-local) at 8 weeks. It is possible that the dosage of one or more of your existing blood pressure medications could be lowered or stopped during the study to make sure that eplerenone does not cause low blood pressure.

If you are eligible and agree to participate, the following will occur:

1) A questionnaire to assess your quality of life will be mailed to you.
2) When the questionnaire is returned to us, eplerenone will be sent to you and you can start it immediately.
    a. Blood work will be repeated in 1 week and again at 4 weeks to assess your kidney function and potassium level. The blood draw will occur in our research office if you are local, and an order will be placed for the blood draw to be performed at your local VA community-based outpatient clinic or hospital if you are non-local.
3) At 8 weeks the questionnaire will again be mailed to you and you will be contacted by a study coordinator. When you return the questionnaire, your participation in the study is complete.
4) When the study is complete, you will return to the same blood pressure medications that you were on at the beginning of the study. It will not be possible to remain on eplerenone since this medication is not on the VA formulary. There is a similar medication, called spironolactone which you can discuss with your provider after the study completion, if you experienced significant benefit from eplerenone.

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

If you have any questions now or at any time during this Research Study, please contact one of the Research Team members listed in question 3 of this form.

8. How long will you be in this research study?

8 weeks

9. How many people are expected to take part in this research study?

Up to 25 subjects will participate in this study.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

10. What are the possible discomforts and risks from taking part in this research study?

Possible risks from participation in this study are very small, but would linclude the following:

Elevated potassium:

Eplerenone can cause an elevation in an electrolyte called potassium. This is called hyperkalemia. If potassium becomes severely elevated, life threatening heart rhythms can occur. Your potassium will be monitored by routine blood tests.

Blood draw:

The risks of drawing blood from a vein include discomfort at the site of puncture; possible bruising and swelling around the puncture site; rarely an infection; and, uncommonly, faintness from the procedure. The risk from a blood draw is considered to be minimal.

Study medication:

Eplerenone is a Food and Drug Administration approved medication for treatment of hypertension. Possible adverse reactions include: headache, dizziness, diarrhea, stomach pain, chest pain, nausea, cough or flu-like symptoms (such as fever, chills, body aches, or unusual tiredness), vaginal bleeding, breast swelling/tenderness, or rash.

Questionnaire: Possible emotional discomfort when answering some of the questions; however, this risk is exceeding small.

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Confidentiality: Confidential information about subjects might be accidentally disclosed. We will use our best efforts to keep the protected health information secure. The risk of accidental disclosure is exceeding small.

Researchers will take appropriate steps to protect any information they collect about you. However there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this consent form or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of any new information that may become available and might affect your decision to remain in this study. This includes, but is not limited to, information that may affect your safety, well-being or medical care.

If you wish to discuss the risks or discomforts described above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 of this form.

11a. What are the potential benefits to you for taking part in this research study?

You might breath better and have more energy from taking eplerenone. You might also enjoy the satisfaction of participating in a research project that could ultimately help others.

11b. How could others possibly benefit from this study?

We hope that in the future other people might benefit from this study because doctors will be able to identify patients who do not feel well after TAVR and help them to live longer and improve their quality of life through the medication eplerenone.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 may benefit if the results of this study are presented at a scientific meeting or published in a scientific journal.

12. What other choices do you have if you do not want to be in this study?

If you choose not to participate in this research study, you will still have your normal clinical care. If you do not want to take part in this study, tell the Principal Investigator and do not sign this Informed Consent Form.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you withdraw from this study, your research information will no longer be collected. However, information that has already been collected will continue to be used to the extent that the researchers have used it in this research study.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- If it is considered important for your medical safety.

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WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

There will be no costs to you for any procedure, treatment or testing done as part of this research study. However, medical care and services provided by the VA that are not being done only for this study (e.g., normal hospital and prescription expenses which are not part of the research study) will be charged to you or your insurance. These costs may not be charged if you are a veteran and you are being treated at the North Florida/South Georgia Veterans Health System (NF/SG VHS), however some Veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to VA-provided medical care and services that are not part of this study."

15. Will you be paid for taking part in this study?

There is no compensation for taking part in this study

16. What if you are injured because of the study?

If you experience an injury or illness as a result of your participation in this VA approved research study, all medical treatment considered necessary by your physician (emergency as well as medical treatment beyond emergency) will be provided by the VA. There will be no cost to you, unless you fail to follow the directions of the study procedures. Care will be provided at a VA medical facility unless the VA medical facility is not capable of providing the care. If this occurs, you will be treated by a private facility or physician and the VA will pay the private facility or physician for the reasonable cost of your care. In some cases the VA may approve private care for a non-veteran

If you do not follow study procedures, you may be treated by the VA on the basis of your veteran's eligibility. If you are not a veteran and have not followed study procedures the VA can only provide limited care at your expense.

No additional money has been set aside for pain, suffering or any money losses you may suffer during your treatment. You have not waived any legal rights by signing this form.

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In the event of a research-related injury, have questions about any discomforts that you experience while participating in this study or if you experience an adverse reaction, please immediately contact the Principal Investigator listed in question 3 of this form during the day and after business hours. If you seek emergency hospitalization in a private hospital because you are unable to come to the VA, have a family or friend contact your study doctor so that the VA can coordinate care with the private hospital.

17. How will your privacy and the confidentiality of your research records be protected?

Information collected about you will be stored in locked filing cabinets and in computers with secure passwords. Only certain people have the legal right to review these research records, and they will protect the secrecy (confidentiality) of these records as much as the law allows. These people include the researchers for this study, certain University of Florida officials, the hospital involved in this research, and the Institutional Review Board (IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). Certain federal agencies such as the Office for Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), or the VA Office of the Inspector General (OIG), that oversee human subject research may also have the legal right to review your records. Otherwise your research records will not be released without your permission unless required by law or a court order.

Researchers will take appropriate steps to protect any information they collect about you. However there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you.

If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.

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SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternatives to being in the study; and how privacy will be protected:

_____ _____

Signature of Person Obtaining Consent Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your privacy will be protected. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

_____ _____

Signature of Person Consenting Date

FOR RESEARCH STAFF

In-person

Telephone