COVER PAGE

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INFORMED CONSENT

Official Study Title:
Defining the Risk of Ventricular Tachycardia in Genetic Forms of Early-Onset Atrial Fibrillation

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Principal Investigator:
M. Benjamin Shoemaker, M.D., M.S.C.I

VUMC Institutional Review Board
Informed Consent Document for Research

Study Title:	Defining the Risk of Ventricular Tachycardia in Genetic Forms of Early-onset Atrial Fibrillation
Version Date:	09/17/2024
PI:	M. Benjamin Shoemaker, M.D., M.S.C.I.; Co-PI: William G. Stevenson, M.D.

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

This study seeks to understand why some patients who are diagnosed with atrial fibrillation (AF) at a young age and have certain genetic mutations are at a higher risk of death. We think that the reason why patients with these specific mutations are at a higher risk of death is because they develop scar in the bottom part of the heart, called the ventricle and this can cause a life-threatening arrhythmia called ventricular tachycardia.

As part of the standard treatment for your arrhythmia, you are being referred for an "ablation" procedure. Your ablation procedure will be performed the same whether or not you agree to be part of this study. Part of your procedure includes pacing maneuvers to try and induce arrhythmias from the atria and ventricles.

If you agree to the study, we will study the electrical signals in your ventricle. This will use the same equipment that was used for the other parts of the ablation procedure. No additional needle sticks or I.V.'s or equipment are needed. We will check to see if there is any scar in your ventricle. Scar is seen by measuring the size of your heart's electrical signals. If scar is found in your ventricle that causes ventricular tachycardia, it can mean you are at higher risk of death in the future from ventricular tachycardia. This is important information for doctors and there are treatments to reduce this risk. This is a potential benefit to you for taking part in this study.

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There are risks for taking part in this study. The risks associated with the research protocol are from moving the catheter around in your ventricle to identify whether you have scar and to locate where arrhythmias are coming from, if you have any. Moving the catheter around may tickle the ventricle which also can cause arrhythmias. There is also a risk of perforation, which means creating a small hole in the heart. However, the additional risk of perforation from the research protocol is negligible compared to the rest of the ablation procedure and it is estimated to be less than 0.4 to 0.1%.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

The purpose of this study is to learn more about how and why certain gene mutations affects patients with early onset atrial fibrillation. Approximately 1 in 10 patients with atrial fibrillation diagnosed before the age of 60 have a change in their genetic code called a mutation, most commonly in a gene called *TTN*. Patients with mutations in *TTN*, or similar genes, have a higher risk of sudden death. We think this is due to ventricular tachycardia and the goal of this study is to test that hypothesis.

You are being referred for a procedure called an "ablation" to treat your atrial fibrillation (AF), premature ventricular contractions (PVCs), or ventricular tachycardia (VT). During the ablation procedure, we will be using catheters to enter the top chamber of the heart (atrium) and/or bottom chamber of your heart (ventricle) to perform the ablation. Your ablation procedure will be performed the same whether or not you agree to be part of this study.

If you agree to this study, we will be moving the catheters from your atrium to your ventricle. These 2 parts of the heart are next to each other. During ablations we routinely move catheters throughout all chambers of the heart. This is easy and low risk. We will check to see if there is scar in your ventricle and we will check to see where any extra beats are coming from. We do this by measuring the size and studying characteristics of the electrical signals.

Another potential risk of taking part in this study is that we identify scar in your ventricle that may indicate you are at risk for life-threatening arrhythmias. That may result in a discussion about whether you may need placement in the future of an implantable cardioverter defibrillator

(ICD, a device under your skin that monitors your heart rhythm and can deliver electric shocks to fix abnormal rhythms).

A potential benefit from this study is that we may learn about why some patients with genetic mutations develop life threatening arrhythmias and learn how to predict and prevent them. This information may be a potential benefit to you.

The information obtained from the study will be made available to others to use for research. To protect your privacy, we will not release your name or other information that can identify you.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:

1) As part of the research protocol, when moving the catheter around your ventricle, there is the risk of causing an arrhythmia and a very small risk of perforation.
2) Radiation Risks: This research may involve additional exposure to radiation from fluoroscopy. This radiation exposure is not necessary for your medical care and is for research purposes only. The total amount of radiation that you will receive by participating in this study is equal to 9 months of radiation from your natural surroundings, or about 4% of the amount allowed in a year for people who are exposed to radiation as part of their work.
3) This study also carries the risk of potential breach of confidentiality (rare). You may have already had a genetic test obtained. One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job. Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees, with the exception of government employers, and military, may not use

your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. To prevent the release of your name and other private information, your information will be given a unique code. Only Dr. Shoemaker and members of the study team will know the code. The key to the code will be kept in a locked file or be placed into a password-protected computer database by study personnel.

4) Anxiety related to the medical implications and prognosis from detecting a potentially disease-causing variant. This is a common issue encountered by members of the study team (Drs. Shoemaker and Katherine Anderson, LCGC) in the Vanderbilt Inherited Arrhythmia and Cardiomyopathy Clinic. They will employ the same approach as used clinically for medical and genetic counseling.

Good effects that might result from this study:

A) The benefit to science and humankind that might result from this study is that we may learn more about how atrial fibrillation occurs, whether patients like you with atrial fibrillation with early diagnosis have a genetic basis for their atrial fibrillatio n and whether there may be effective treatments for any genetic finding you may or may not have.

B) We may find out new information about your potential risk for other heart problems. This may result in changes to your medical care.

Procedures to be followed:

If you agree, a member of the study team to tell you about the study. The consent form will be given to you in person, emailed, or mailed to you. If you decide to take part in the study, you will complete the e-consent or sign the paper consent. You will be given a copy for your records. If you have questions about them, we will answer them in-person, by phone, or by email. On your scheduled day, you will come to the Vanderbilt Heart and Vascular Institute to get your ablation procedure. You will undergo standard preparations for an atrial fibrillation, PVC, or VT ablation, depending on which procedure is scheduled to be performed as part of your clinical care. As part of the ablation procedure, your doctor will place I.V's in the blood vessels in your leg. The I.V's will be used for placing the tools used for the procedure, drawing blood, and measuring your blood pressure. Some of the tools used are small pacing catheters (wires) to study your heart's

electrical system and induce arrhythmias. We will use the same tools we use for the ablation procedure to create a map of your ventricle to check to see if there is any evidence of scar and perform a standard rapid pacing protocol to induce any arrhythmias. You may go home after the procedure or spend the night in the hospital. This is at the discretion of your doctor and participation in the research program does not affect the decision to go home or stay overnight. Nurses or study staff will assist you the first time you get out of bed and walk after the procedure. Your doctors will see you that morning and let you go home if they think you are ready.

Payments for your time spent taking part in this study or expenses:
None

Costs to you if you take part in this study:
There is no cost to you for taking part in this study.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at Vanderbilt to treat the injury. There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact study coordinators, Dakota Grauherr, RN at 615-714-8674 or Diane Crawford, RN at 615-936-6069 or if you cannot reach the research staff, please call Dr. Ben Shoemaker at 615- 322-2318.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:

Your study doctor may choose to take you out of this study if they feel it is not in your best interest. Women of childbearing potential will undergo a pregnancy test the morning of the study visit. If the test indicates you are pregnant, you will be removed from the study but there is a chance you be able to participate in the study after your delivery.

If your ablation procedure is not completed for any reason, you will be withdrawn. The doctor may take you out of this study if you ask to be taken out of the study. You may also be withdrawn if your clinical condition changes prior to the ablation and you are no longer eligible. You may also be taken out of this study for other reasons. You will be told why if this happens.

You will not be removed from the study without being given a reason why.

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor. Your standard heart health treatment will not change in any way if you choose not to be in this study. At any time, you may ask to have your samples destroyed if you request them to be. You should contact Dr. Ben Shoemaker in writing at 2525 West End Avenue Suite 370-A Nashville, TN 37203/ # 615-322-2318 to have your sample destroyed and no longer used for research. We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.

Confidentiality:
Your study records and data will be stored in a secure database. The database will reside in a password-protected secure web site supported by Vanderbilt. Only study personnel will have access to the database. Information in the database that will identify you will only be available to study personnel.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Shoemaker and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Your samples/study results may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt Univers ity Medical Center, and/or others. If this happens, there are no plans to provide money to you.

Study Results:
As part of the study, Dr. Shoemaker may share the results of your study and/or non-study linked bloodwork, as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, and the National Institutes of Health. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your protected health information (PHI) private.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and

that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact informa t ion provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

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You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

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STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date	Signature of patient/volunteer

Consent obtained by:

Date	Signature
Time	Printed Name and Title