Informed Consent Cover Page for FDAAA consent posting:

Official Title:	NHLBI Transmural Electrosurgery LeafLet Traversal and Laceration Evaluation (TELLTALE) BASILICA-TAVR Trial
NCT number:	NCT05666713
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Catholic Health
St. Francis Hospital
& Heart Center®

INFORMED CONSENT FORM

Sponsor / Study Title:	**Office of Clinical Director, National Heart Lung and Blood Institute, National Institutes of Health / NHLBI Transmural Electrosurgery LeafLet Traversal And Laceration Evaluation (TELLTALE) BASILICA-TAVR Trial**
Protocol Number:	**000673H**
Principal Investigator: (Study Doctor)	**Jaffar Khan, MD**
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KEY INFORMATION ABOUT THIS RESEARCH

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study. Your participation in this study is voluntary. This study is taking place at more than one site.

You are being asked to take part in a research study at the site listed on this page of this consent document.

This study is sponsored by the National Institutes of Health (NIH). This means that the scientists from NIH will review your and other participants data obtained during this study and monitor the safety of the study.

This section provides the information we believe is most helpful and important to you in making your decision about participating in this study. Additional information that may help you decide can be found in other sections of the document. Taking part in research is your choice.

You have aortic stenosis or you have failure of a surgical aortic valve. That means the main heart valve does not function properly, causing your heart to work too hard. Your heart specialists recommend you have transcatheter aortic valve replacement (TAVR) because the risk of open heart surgery is too high. However, they believe standard TAVR cannot be safely performed using standard methods. Your specialists are concerned that standard TAVR may block your coronary arteries (arteries that supply blood to the heart muscle), by pushing your existing heart valve tissue outwards. This is dangerous and could cause death.

To try to make TAVR a better option for you, your doctors are offering a new technique called BASILICA (Bioprosthetic Scallop Intentional Laceration to prevent Iatrogenic Coronary Artery obstruction during transcatheter aortic valve replacement), invented by the NHLBI (National Heart, Lung, and Blood Institute), an institute of the NIH. NHLBI and Transmural Systems, a device manufacturing company, have developed an investigational BASILICA system (TELLTALE guidewire system) to apply electricity to slice the leaflets in your aortic valve that risk blocking coronary arteries during TAVR. The BASILICA procedure has been performed with physician-modified tools that were not specifically designed for the procedure. In this study we are testing a system specially designed for BASILICA (the TELLTALE Guidewire System) that we hope will be safe and effective.

In every other way, your TAVR procedure will be performed in the standard way with FDA (Food and Drug Administration)-approved valve.

If you agree to participate, you would be among the first participants in the world using the TELLTALE Guidewire System for the BASILICA-TAVR procedure. We believe the TELLTALE guidewire system will enable your study doctors to perform BASILICA-TAVR safely, to treat your aortic valve failure without open heart surgery. Reasonably foreseeable risks include:

- Failure to cross or split the aortic valve leaflets, requiring a different approach to treatment, including stopping and not performing TAVR
- Failure to prevent coronary artery blockage despite successful BASILICA-TAVR, which risks heart attack and death
- Embolization (release) of air, valve debris, or clot to your heart, brain, organs, arms, or legs, possibly causing symptoms or even stroke or heart attack.
- Dangerously low blood pressure, possibly requiring insertion of artificial heart pumps (“mechanical circulatory support”)
- Tearing of the heart valve leaflet causing dangerously low blood pressure, or displacement of the torn leaflet into your heart, brain, or the rest of your body
- Damage to another (“mitral”) heart valve requiring emergency catheter or surgical repair
- Accidental entry into a different part of the heart, such as the left atrium
- Damage or puncture of your coronary arteries (the arteries that supply blood to the heart), or other arteries, requiring emergency catheter or surgical repair
- Failure, fracture, or damage to the research TELLTALE Guidewire System requiring catheter-based or surgical repair

- Complications of catheter procedures including bleeding, blood transfusion, or blood vessel damage
- Heart congestion, fluid overload causing breathing problems even requiring connection to a breathing machine
- Dangerous heart rhythms
- Radiation injury including skin ulcers that fail to heal, or cancer
- Allergic reaction to anesthesia, x-ray contrast medications, or materials in the research TELLTALE guidewire system
- Heart attack
- Stroke or transient ischemic attack or paralysis
- Permanent disability
- Death

After the BASILICA-TAVR procedure using TELLTALE guidewire system, we would follow you closely, with standard care after TAVR. This would involve a follow-up return trip to this medical center 30 days after the procedure for your study doctor to conduct a physical examination, blood tests, questionnaires, and to take pictures of your heart using ultrasound ("echocardiography"). It would also require a follow-up telephone call or visit 90 days after the procedure.

The remaining document will now describe the research study in more detail. This information should be considered before you make your choice. Members of the study team will talk with you about the information in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research interventions in which they would want to participate. Take the time you need to ask any questions and discuss this study with study staff, and with your family, friends, and personal health care providers.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason without penalty. In either case, you will not lose any benefits to which you are otherwise entitled. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

WHY IS THIS STUDY BEING DONE?

You have aortic stenosis or you have failure of a surgical aortic valve, which means that your main heart valve does not function properly, causing your heart to work too hard.

Your heart specialists recommend you have transcatheter aortic valve replacement (TAVR) because the risk of open heart surgery is too high. However, they believe TAVR cannot be safely performed using standard methods. Your specialists think TAVR may block your coronary arteries (arteries that supply blood to the heart muscle), by pushing your existing heart valve tissue outwards. This is dangerous and could cause death.

We are inviting you to join this research study because your heart specialists believe you may benefit from a new technique called “Bioprosthetic or native Scallop Intentional Laceration to prevent Iatrogenic Coronary Artery obstruction - transcatheter valve replacement aortic” or “BASILICA-TAVR” for short, and that uses an investigational TELLTALE Electrosurgical Guidewire System.

Figure 1 left shows that in patients at-risk like you, TAVR can cause a coronary artery to be blocked. Figure 1 right shows that BASILICA can split a leaflet and protect a threatened coronary artery after TAVR.

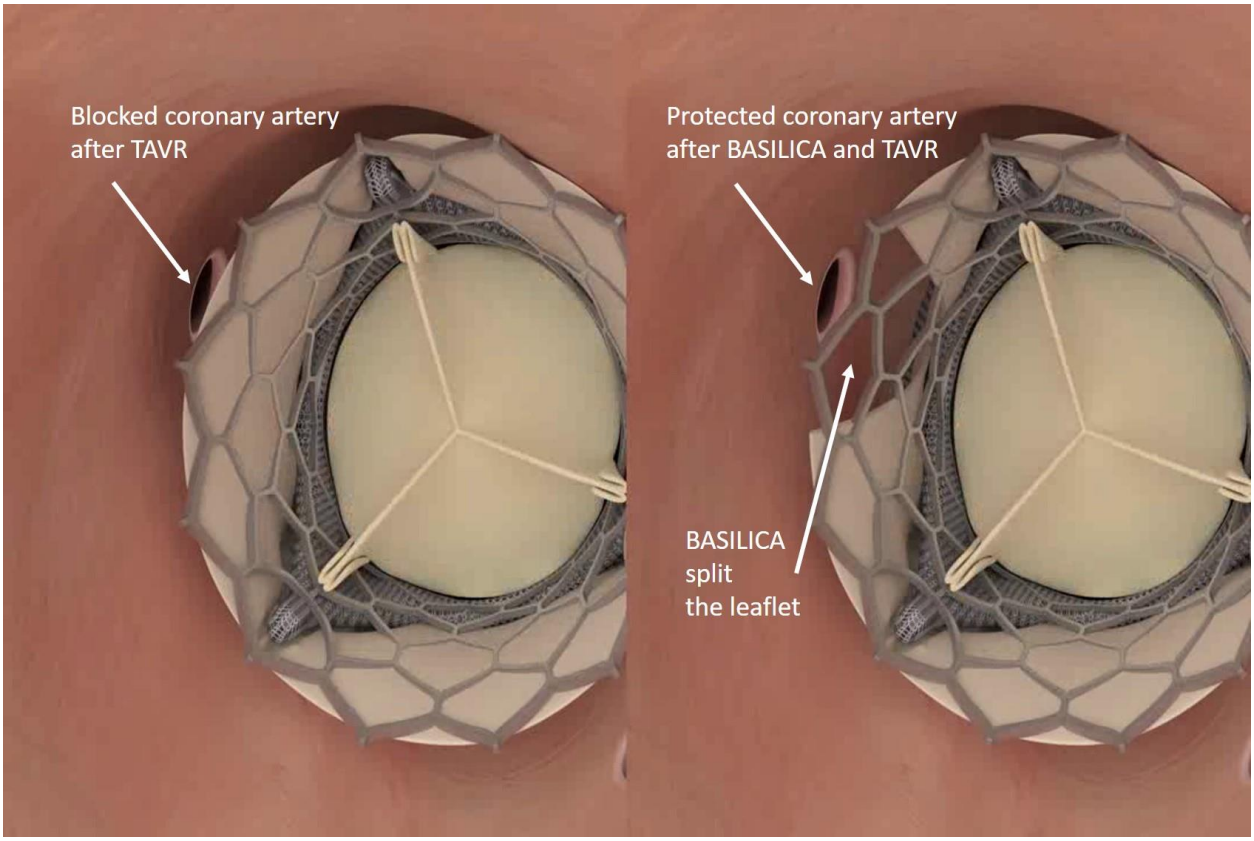

Figure 1. TAVR without (left) and with (right) BASILICA to prevent blockage of a coronary artery

TELLTALE is an investigational catheter system (medical device used without open heart surgery) that has not received FDA approval. TELLTALE applies electricity to split your aortic valve tissue, in order to prevent TAVR from blocking your coronary arteries.

Figure 2 shows how the TELLTALE device slices your valve leaflet before TAVR, without requiring surgery. The sliced leaflet creates space for blood to flow to your coronary arteries after TAVR.

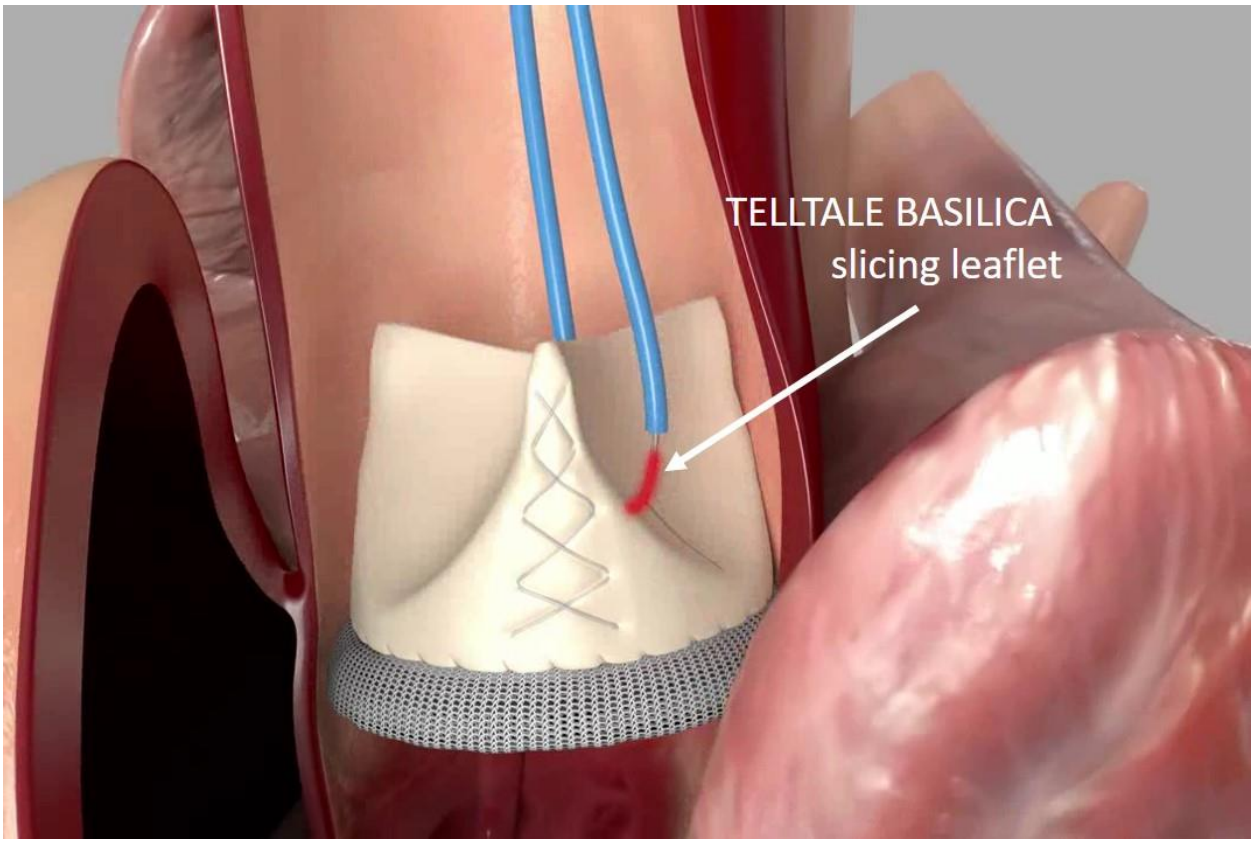

Figure 2. BASILICA using the TELLTALE guidewire system.

Physician-scientists at NHLBI and participating medical centers originally developed the BASILICA procedure by modifying commercially available guidewires and catheters at the bedside during the TAVR procedure. They studied the BASILICA procedure carefully in a small number of patients, and they also taught dozens of physicians worldwide how to perform the BASILICA procedure. The BASILICA procedure has been used in medical care on thousands of patients.

NHLBI and Transmural Systems then developed a guidewire specially designed for BASILICA, called the TELLTALE Guidewire System. We believe the TELLTALE Guidewire System will be safer and easier to use than the original way. By testing the TELLTALE Guidewire System during your BASILICA-TAVR procedure, we seek to demonstrate that the TELLTALE Guidewire System is as safe and effective as we expect based on tests in the laboratory. We hope that TELLTALE can be used by other doctors in the future for BASILICA-TAVR.

We also want to write about the results of this BASILICA-TAVR procedure using the TELLTALE Guidewire System in medical journals to help doctors take care of other patients, without sharing your identity.

WHAT WILL HAPPEN DURING THE STUDY?

If you agree to participate in this study, your study doctors will perform transcatheter aortic valve replacement (TAVR) using the investigational TELLTALE Guidewire system for BASILICA (Bioprosthetic or native Aortic Scallop Intentional Laceration to prevent Iatrogenic Coronary Artery obstruction) technique.

The BASILICA-TAVR procedure is performed in the hospital Hybrid operating room where all TAVR cases are performed. We expect the BASILICA-TAVR procedure will take approximately one to three hours. The procedure is performed with you either completely asleep (general anesthesia) or partially asleep (sedation). Doctors performing the BASILICA procedure use catheters (tubes) and wires, while watching X-rays and ultrasound, to cross and split your aortic valve leaflet. Then they implant a standard FDA-approved replacement aortic valve. The study doctors expect that splitting the leaflets of your damaged aortic valve will prevent the blockage of blood flow into the coronary arteries (that supply blood to the heart muscle).

Your BASILICA-TAVR procedure may be observed by physician-investigators and manufacturer representatives of the TELLTALE Guidewire System, either in-person or remotely via secure computer-based video cameras and microphones. The observers can give advice, if needed, to your doctors performing the procedure. The videos will be recorded to later secure review for research.

Afterwards you receive standard after-TAVR care.

You also will undergo at a follow-up echocardiogram after one month, as well as other non-invasive tests.

Below is a schedule of study activities.

Timepoint	Activity and explanation
Before the procedure	Evaluation of your aortic valve regurgitation, including cardiac CT (computed tomography) scan, coronary arteriography (procedure to visualize the inside of blood vessels and organs), electrocardiogram (a recording of the heart's electrical activity), echocardiogram (an ultrasound of the heart), blood tests, questionnaires, and walking tests. These are standard tests whether or not you participate in this study.
Day 0 (during the procedure)	BASILICA-TAVR procedure using TELLTALE, including coronary arteriography, ultrasound of the heart and coronary artery catheter placement, blood tests and electrocardiogram.
Inpatient (until discharge)	Standard medical care after BASILICA-TAVR including electrocardiogram, physical examination and blood tests. These are standard tests whether or not you participate in this study. Check for problems ("adverse events").

Day 30 (±3 weeks)	Standard medical care after BASILICA-TAVR including physical examination, blood tests, echocardiogram and questionnaires. Check for problems ("adverse events").
Day 90 (±3 weeks)	Visit or telephone call to check for problems ("adverse events").

HOW LONG WILL THE STUDY TAKE?

If you agree to take part in this study, your involvement is expected to last for 90 days. There is one in-patient visit for the TAVR procedure, one routine out-patient visit required 30 days after TAVR. This out-patient visit may take most of the day to complete required tests. There will be a final visit or telephone call at 90 days. We will request the medical records and echocardiogram be sent to the study doctors.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

Up to 180 people will be screened for this procedure.

90 people will undergo BASILICA-TAVR with the TELLTALE Guidewire System.

WHAT ARE THE RISKS AND DISCOMFORTS OF BEING IN THE STUDY?

The risks of the TELLTALE guidewire system used for BASILICA-TAVR procedure are based on our experience performing BASILICA using non-dedicated tools that physicians modify at the bedside.

It can be hard to tell whether the danger is caused by the TELLTALE Guidewire System, by the BASILICA procedure, or by the TAVR procedure. We believe the risks associated with the whole procedure may include:

Risks
Death
Stroke or transient ischemic attack (a temporary period of symptoms similar to those of a stroke) or paralysis.
Heart attack.
Emergency heart surgery.
Permanent disability.
Failure to cross or split the aortic valve leaflets, requiring a different approach to treatment, including stopping and not performing TAVR.
Failure to prevent coronary artery blockage despite successful BASILICA-TAVR, which risks heart attack and death.
Embolization (release) of air, valve debris, clot to your heart, brain, organs, arms, or legs, possibly causing symptoms or even stroke or heart attack.
Dangerously low blood pressure and failure of the heart to pump effectively, possibly requiring cardiopulmonary resuscitation (CPR), insertion of a breathing machine, insertion of artificial heart pumps ("mechanical circulatory support"), or emergency surgery.

Risks
Tearing of the heart valve leaflet causing dangerously low blood pressure, or displacement of the torn leaflet into your heart, brain, or the rest of your body.
Damage to another (“mitral”) heart valve requiring emergency catheter or surgical repair.
Accidental entry into a different part of the heart, such as the left atrium.
Damage or puncture of your coronary arteries (the arteries that supply blood to the heart), or other arteries, requiring emergency catheter or surgical repair.
Failure, fracture, or damage to the research TELLTALE Guidewire System, causing electrical damage to your heart, or requiring catheter-based or surgical repair.
Complications of placing large catheters (tubes) into the arteries and veins through the skin, including bleeding into the retroperitoneal space (the space of the lower back and behind the abdominal lining), hematoma (bruise), fistula (an abnormal connection between two organs), chronic nerve damage or pain, or other access site injury.
Bleeding leading to anemia (low blood) and blood transfusion.
Heart congestion, high blood pressure, or fluid overload causing breathing problems even requiring connection to a breathing machine.
Heart rhythm abnormalities that can be permanent or temporary, atrial fibrillation, atrial flutter, ventricular fibrillation that can require treatment including electrical shocks or a temporary or permanent pacemaker.
Radiation injury including skin ulcers that fail to heal, or cancer.
Allergic reaction to anesthesia, contrast media, or TELLTALE study device materials.
Blood clots that can affect your brain or heart or lungs or legs other parts of your body causing symptoms like a heart attack or stroke or breathing difficulty or limb swelling.
Infection including of your TAVR valve or some other part of your body (including blood vessels, catheter puncture sites, lung, urinary tract) in the days, weeks and years after TAVR.
Infection of the heart valves (“endocarditis”).
TAVR valve failure to function properly, including leakage causing heart failure or causing damage to your blood cells (“hemolysis”), or causing clotting or thickening of the leaflets.
Other failure of your heart valve to function properly.
Kidney damage from the TAVR or BASILICA procedure or from contrast dye, that can be reversible or permanent, requiring temporary or permanent dialysis or medical treatment.
Breathing (“respiratory”) insufficiency failure requiring oxygen therapy, mechanical support or mechanical ventilation (life support).
Damage to your heart or lungs causing fluid buildup around your heart, blood or fluid or gas buildup around your lungs, or lung collapse, requiring treatment.
Abnormal blood tests including serum chemistry tests (creatinine, troponin), electrolyte imbalance, and including hematology tests (hemoglobin, hematocrit, platelets, white blood cells).
Pain including chest pain, angina, back pain, access site pain, neuropathy (nerve pain), and generalized pain.

We believe these risks are acceptable when considering the seriousness of your heart valve disease, and the high risk of alternatives such as open heart surgery or of TAVR without BASILICA.

What are the risks related to pregnancy?

If you are able to become pregnant, we will ask you to have a pregnancy test before beginning this study. TAVR, and the radiation required for TAVR, may be dangerous for a fetus (baby).

If you become pregnant after the TAVR, you can remain in the study because there are no invasive or dangerous procedures required for study follow-up.

What are the risks of radiation from being in the study?

Exposure to radiation is necessary for TAVR.

Additional exposure to radiation is necessary for BASILICA using the TELLTALE Guidewire System.

During your participation in this research study, you may be exposed to approximately 30 minutes of extra X ray fluoroscopy from BASILICA using the TELLTALE Guidewire System. The amount of radiation exposure from these procedures is equal to approximately 3 rem. A rem is a unit of absorbed radiation.

Every day, people are exposed to low levels of radiation that come from the sun and the environment around them. The average person in the United States receives a radiation exposure of 0.3 rem per year from these sources. This type of radiation is called "background radiation." No one knows for sure whether exposure to these low amounts of radiation is harmful to your body.

The fluoroscopy that you get in this study will expose you to roughly the same amount of radiation as 10 years of background radiation. Most of the time, this amount of extra radiation is not harmful to you. However, scientists believe that being exposed to too much radiation can cause harmful side effects. This could include getting a new cancer. We estimate that this could happen in about 1 out of every 1000 people who get a very large amount of extra radiation.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

You might not benefit from being in this study.

You are at high risk of coronary obstruction if a TAVR procedure were to be performed without BASILICA.

We believe that BASILICA using the TELLTALE Guidewire System may reduce your risk of coronary artery obstruction to facilitate a TAVR procedure.

Are there any potential benefits to others that might result from the study?

In the future, other people might benefit from this study because TELLTALE guidewire system used for the BASILICA-TAVR procedure may help to treat their aortic valve failure.

WHAT OTHER OPTIONS ARE THERE FOR YOU?

Before you decide whether or not to be in this study, we will discuss other options that are available to you.

Instead of being in this study, you could continue medication-only treatment of your aortic valve disease. In general patients do poorly when treated only with medications for aortic valve stenosis (blockage).

You could undergo open heart surgery to replace the failing aortic valve. You are at high or prohibitive risk of death from this option. You could request your heart team physicians consider an alternative to BASILICA, such as placing stents in the coronary arteries during TAVR, which risks failure and clotting and possibly preventing future coronary artery catheter treatments. You could also request your physicians perform "standard" BASILICA without using the investigational TELLTALE Guidewire System.

In summary, you can discuss the following other options with your physicians and with your study doctors:

(1) Continued treatment with medications only
(2) Open heart surgery to replace your aortic valve
(3) TAVR and stent implantation to try to prevent coronary artery obstruction
(4) TAVR and BASILICA without participating in research.

DISCUSSION OF FINDINGS

New information about the study

If we find out any new information that may affect your choice to participate in this study, we will get in touch with you to explain what we have learned. This may be information we have learned while doing this study, or information we have learned from other scientists doing similar research in other places.

Return of research results

If you request the results of this research study, we will send you a summary of the results and what they mean. You may not receive the individual results.

EARLY WITHDRAWAL FROM THE STUDY

You may withdraw from this research study at any time. To do so, please contact the study doctor at the telephone number listed on the first page of this consent document. The study doctor or the sponsor can stop your participation at any time without your consent.

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR DATA

As part of this study, we are obtaining data from you. All your data obtained during this study will be transferred to NIH. Although this study is taking place at more than one site, researchers at NIH will review and analyze the data from all study participants, no matter where they underwent the BASILICA-TAVR procedure.

It is important for you to know that **your name and other personal identifiers will be kept attached to your medical images and your medical records** when they are sent to NIH and when they are stored at NIH.

Will your data be saved for use in other research studies?

As part of this study, we are obtaining data from you. We plan to store and use these data for studies other than the one described in this consent form that are going on right now, as well as studies that may be conducted in the future. The data will be kept in a way that we will still know that they came from you (that is, they will be identifiable to us). If we use your identifiable data for future research, our study will be reviewed and approved by an Institutional Review Board who will make sure that we are protecting your confidentiality. These future studies might help us better understand heart valve disease or other diseases or conditions. This could include studies to develop other research tests, treatments, drugs, or devices, that may lead to the development of a commercial product by the NIH and/or its research or commercial partners. There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you.

I give permission for my identifiable data to be stored and used by the study team for future studies as described above.

_____ Yes _____ No
Initials Initials

Will your data be shared for use in other research studies?

We may share your coded data with other researchers. If we do, while we will maintain the code key, we will not share it, so the other researchers will not be able to identify you. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at NIH, other research centers and institutions, or commercial entities.

In some cases, it may help other researchers to know that the data were collected from you (that is, they will have your identifiers). If we share your identity with other researchers, their study will be reviewed and approved by an Institutional Review Board who will make sure that the study team is protecting your confidentiality.

I give permission for my identifiable data to be shared with and used by other researchers for future studies.

_____ Yes _____ No
Initials Initials

In addition to the planned use and sharing described above, we might remove any labels from your data that might identify you (that is, anonymize them), and use them or share them with other researchers for future studies at the NIH or other places. When we or the other researchers use your anonymized data for these projects, there will be no way to know that they came from you. We want to make sure that you understand that this is a possibility if you participate in this study. Once we do this, we would not be able to remove your data from these studies or prevent their use in future studies because we would not be able to tell which data belong to you.

Can you change your mind about use and sharing for future research?

If you change your mind and do not want us to store and use your data for future research, you should contact the study team member identified at the top of this document. We will do our best to comply with your request but cannot guarantee that we will always be able to destroy your data. For example, if some research with your data has already been completed, the information from that research may still be used. Also, for example, if the data have been shared already with other researchers, it might not be possible to withdraw them.

In addition to the planned use and sharing described above, we might remove all identifiers and codes from your data and use or share them with other researchers for future research at the NIH or other places. When we or the other researchers access your anonymized data, there will be no way to link the data back to you. We will not contact you to ask your permission or otherwise inform you before we do this. We might do this even if you answered "no" to the above questions. If we do this, we would not be able to remove your data to prevent their use in future research studies, even if you asked, because we will not be able to tell which are your data.

How Long Will Your Data be Stored by the NIH?

Your data may be stored by the NIH indefinitely.

Risks of Storage and Sharing of Data

When we store your data, we take precautions to protect your information from others that should not have access to it. When we share your data, we will do everything we can to protect your identity, for example, when appropriate, we remove information that can identify you. Even with the safeguards we put in place, we cannot guarantee that your identity will never become known or someone may gain unauthorized access to your information. New methods may be created in the future that could make it possible to re-identify your data.

PAYMENT

Will you receive any type of payment for taking part in this study?

You will not receive any payment for taking part in this study.

This study does not offer reimbursement for, or payment of, travel, lodging or meals.

COSTS

Will taking part in this research study cost you anything?

Yes.

You and your insurance company are responsible for the costs of medical care involved in TAVR and taking pictures of your heart. The study device used in the study will be provided by the manufacturer, Transmural Systems, without charge to you, your insurance or St. Francis Hospital & Heart Center.

CONFLICT OF INTEREST

The National Institutes of Health (NIH) reviews NIH staff researchers at least yearly for conflicts of interest. This process is detailed in a COI Guide. You may ask your research team for a copy of the COI Guide or for more information. Members of the study team who do not work for NIH are expected to follow these guidelines or the guidelines of their home institution, but they do not need to report their personal finances to the NIH.

The National Institutes of Health and the study team for this study have co-developed TELLTALE Guidewire System for the BASILICA-TAVR procedure being used in this study. This means it is possible that the results of this study could lead to payments to NIH. By law, the government is required to share such payments with the employee inventors. You will not receive any money from the development of TELLTALE Guidewire System.

The NIH and the study team for this study are using TELLTALE Guidewire System co-developed with Transmural Systems through a joint study with your study team and the company. The company may also provide financial support for this study to your enrolling site.

Transmural Systems is providing TELLTALE Guidewire System for the BASILICA-TAVR procedure to conduct this study to NIH without charge. No NIH investigator involved in this study receives payments or other benefits from any company whose drug, product or device is being tested. NIH investigators may be required to receive royalty payments in the future related to TELLTALE guidewire system devices. In addition, there are some research partners not associated with the NIH working on this study who may receive payments or benefits, limited by the rules of their workplace.

The PI also has ownership interest in Transmural systems, the parent company, and ownership interest in TELLTALE the subsidiary company. As a result, the investigator may benefit financially from a successful study.

The physicians and staff of St. Francis Hospital & Heart Center ® are being compensated for their research time to perform research activities associated with this study. Additional steps have been taken to manage the potential conflict of interest that these financial arrangements may create. Please speak with your study doctor if you have any questions about this.

CLINICAL TRIAL REGISTRATION and RESULTS REPORTING

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.

NCT #:05666713.

HIPAA/CONFIDENTIALITY

There is no expiration date to this consent. If you decide you no longer would like to participate in this study, you may withdraw without any penalty or change in your health care. If you chose to withdraw your authorization to participate in this study, you are asked to notify the study doctor in writing at the address listed on the first page of this form of your decision to no longer participate.

If you decide to no longer to participate in this study, the study staff and study doctor will stop collecting your personal health information. However, information that is related to safety data or an adverse event will continue to be submitted to the study doctor if you decide to no longer participate. The information that was already collected will continue to be used to evaluate the study results, however no additional information will be collected or used.

The information that is disclosed to a recipient may be redisclosed if that recipient is not required by law to protect the privacy of the information.

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The study doctor, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Advarra Institutional Review Board (IRB) will be able to inspect and copy confidential study-related medical records which identify you by name. This means that absolute confidentiality cannot be guaranteed. When results of this research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified.

Will your medical information be kept private?

Information collected for this study is protected by the US Privacy Act of 1974.

In most cases, the NIH will not release any identifiable information collected about you without your written permission. However, your information may be shared as described in the section of this document on sharing of data, and as further outlined in the following sections.

Your name, birthdate, and medical record number will be kept in your medical records when they are sent to NIH for research planning and analysis. This includes your heart CT scans, your heart ultrasounds, and your X-ray (fluoroscopy) pictures. We believe this is safer and protects against mis-identification.

There is a chance your records and identifying information will be disclosed by accident. However, we think that this risk is small.

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- Advarra IRB, the Human Research Protection Programs at NIH and participating sites, and the Data and Safety Monitoring Board.
- Qualified representatives at the study site where your TELLTALE BASILICA_TAVR procedure is performed, as well contractors and representatives from the National Heart, Lung, and Blood Institute, who will examine your medical and research records to make sure they are accurate.
- The NHLBI CT and Fluoroscopy core Laboratories.

Your research data and research medical records may be shared with qualified representatives from Transmural Systems, but only after your personal identifiers have been removed and replaced with a code to protect your identity.

Transmural Systems representatives will be present during your BASILICA-TAVR procedure, and may learn your identity that way.

When results of an NIH research study are reported in medical journals or at scientific meetings, the study participants who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission.

If NIH shares your data with other researchers, we will remove your identifiers before sharing your data. You should be aware that there is a slight possibility that someone could figure out the information is about you.

The researchers conducting this study and the NIH follow applicable laws and policies to keep your identifying information private to the extent possible. However, there is always a chance that, despite our best efforts, your identity and/or information about your participation in this research may be inadvertently released or improperly accessed by unauthorized persons.

In most cases, the NIH will not release any identifiable information collected about you without your written permission. However, your information may be shared as described in the section of this document on sharing of data, and as further outlined in the following sections.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality.

Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

Federal Privacy Act

The Federal Privacy Act generally protects the confidentiality of research information that is collected or provided to the NIH under the authority of the Public Health Service Act during your participation in this research study. This study's data will be stored under system 09-25-0200, Clinical, Basic and Population-based Research Studies of the NIH. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to NIH staff (such as contractors and volunteers), to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV (human immunodeficiency virus) partner notification, for infectious disease or abuse or neglect reporting, to morbidity, mortality, disease, or tumor registries, when authorized by the Secretary of HHS (Department of Health and Human Services), or when the NIH is involved in a lawsuit. However, NIH will only release information about you if it is permitted by both the Certificate of Confidentiality and the Privacy Act. If you do not want to share your information with us, then you cannot participate in this study.

WHAT HAPPENS IF YOU ARE INJURED BECAUSE YOU TOOK PART IN THIS STUDY?

If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this study. If you tell the study team that you think you have been injured then they will help you get the care you need.

If you are injured from procedures done for the purpose of this study, **NHLBI (the sponsor) will not pay for those medical expenses necessary to treat your injury that are not covered by your medical insurance or any other third-party coverage**. You will not lose any of your legal rights or release NHLBI (the sponsor), the Investigator (study doctor), the study team, or study site from liability for mistakes by signing this consent document.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the study doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00068292.

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing this consent document. I will receive a copy of this signed consent document.

_____

Participant's Printed Name

_____ _____

Participant's Signature Date/Time

_____

Printed Name of the Person Conducting the Consent Discussion

_____ _____

Signature of the Person Conducting the Consent Discussion Date/Time