Informed Consent Form:

Left Atrial Posterior Wall Isolation in Conjunction with Pulmonary Vein Isolation for Treatment of Persistent Atrial FibrilLation (PIVoTAL) Trial

Version 1.3 (March 05, 2019)

NCT03057548

Cover Page Date: March 05, 2019

Dignity Health.

EXPERIMENTAL SUBJECTS BILL OF RIGHTS
(California)

You have been asked to participate as a subject in a medical experiment. Any person who is requested to consent to participate as a participant in a research study involving a medical experiment, or who is requested to consent on the behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment;
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
3. Be given a description of any attendant discomforts and risks reasonably to be expected from your participation in the experiment;
4. Be given an explanation of any benefits reasonably to be expected from your participation in the experiment;
5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to you, and their relative risks and benefits;
6. Be informed of the avenues of medical treatment, if any, available to you after the experimental procedure if complications should arise;
7. Be given an opportunity to ask any questions concerning the medical experiment or the procedures involved;
8. Be instructed that consent to participate in the experimental procedure may be withdrawn at any time and that you may discontinue participation in the medical experiment without prejudice;
9. Be given a copy of this form and the signed and dated written consent form;
10. Be given the opportunity to decide to consent or not to consent to the medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on your decision.

I have read the information contained above in the "Experimental Subject's Bill of Rights".

Name of Subject (Please Print)	Date:
Subject Signature:	

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

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TITLE:	Left Atrial Posterior Wall Isolation in Conjunction with Pulmonary Vein Isolation for Treatment of Persistent Atrial Fibrillation (PIVoTAL) Trial
PROTOCOL NO:	Version 1.7
SPONSOR:	Investigator Sponsored
PRINCIPAL INVESTIGATOR:	Arash Aryana, M.D.
SITE(S):	Mercy Medical Group, a service of Dignity Health Medical Foundation and Mercy General Hospital
STUDY-RELATED PHONE NUMBERS:	
COORDINATOR:	Shelley Allen, RN 916-453-2626 (Mon.-Fri. 08:30 a.m. – 5:00 p.m.)
INVESTIGATOR:	Arash Aryana, MD 916-736-2323 (24 hours/7 days per week)
SUB-INVESTIGATORS:	P. Gearoid O'Neill, MD 916-736-2323
	Mark Bowers, MD 916-736-2323

Introduction

You are being given information about becoming a volunteer in a research study. You may qualify for participation in this study because you have a heart condition in which the upper chambers of your heart beat irregularly. This condition is known as atrial fibrillation (AF.) Because your AF lasts for a long time it may be called persistent/longstanding atrial fibrillation. You may qualify for participation if your doctor believes that you need a catheter ablation procedure to treat your atrial fibrillation.

Catheter ablation is performed by applying radiofrequency (RF) energy ("heat") or cryoablation (extreme cold) to damage small areas of heart tissue that are causing the abnormal heart rhythm. A catheter ablation procedure (whether it is via RF or cryo) is not experimental; it is one of the standard forms of treatment for atrial fibrillation.

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This informed consent form explains why the research is being performed and what your role will be if you decide to participate. Your participation in this study is completely voluntary. This form also talks about the possible risks to you if you decide to take part in this study.

Please read this form, and feel free to ask your study doctor any questions you may have about the information. This consent form may contain some words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not understand.

You will be given the chance to have your questions answered before you decide if you want to take part in the study.

If you agree to be in the study, you will need to sign this form. You will be given a copy of this consent form to keep. Taking part in this study is entirely voluntary. You do not have to be in this study to be treated for your illness or condition.

What is the purpose of this study?

The purpose of this study is to learn if ablation of the posterior left atrial wall (PLAW) along with pulmonary vein isolation (PVI) will reduce the chance of AF recurrence in patients with persistent AF one year after an ablation in comparison to a PVI ablation procedure alone.

What will happen if you take part in this research study?

If your doctor finds that you qualify, and you decide to take part in this study, the following procedure(s) will be performed.

Your doctor may choose to ablate your pulmonary veins using radiofrequency (RF) or cryoablation, or a combination of both. During an RF catheter ablation procedure, catheters (long wires that can be moved around within the heart) are moved to the areas of the heart causing the arrhythmia. Using one of these catheters, high frequency energy is applied to the heart tissue ("burns or ablates" the tissue) which is abnormal and thought to play a role in continuing AF.

If a cryoablation is being performed, a catheter with a balloon at the tip is guided to the opening of each pulmonary vein and extreme cold is applied through the balloon to the pulmonary vein tissue.

In most patients, the pulmonary veins (located in the left upper chamber of the heart) cause atrial fibrillation. However in patients with AF of long duration such as yourself, other parts of the heart may play a significant role in allowing atrial fibrillation to

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continue. Some investigators believe that the cause and continuation of persistent AF is related to changes in the tissue of the posterior left atrial wall of the heart.

In this study, patients will be randomly chosen to have ablation of the pulmonary veins alone and others may be chosen to have ablation of the pulmonary veins as well as the posterior lateral atrial wall.

While in the study you will have the following tests, procedures, medication management and follow-up visits, which are all standard of care:

- Recording of your medical history (CHA_2DS_2-VsC score; duration of AF and number or previous cardioversions);
- Review of your symptoms during atrial fibrillation, using the CCS-SAF score [Canadian Cardiovascular Society-Severity of Atrial Fibrillation score];
- Recording of your cardiovascular (heart and blood vessels) medication history (history of antiarrhythmic drugs [AADs], duration of AAD use);
- Transthoracic echocardiogram (TTE) within the previous year, which uses ultrasound waves to image your heart through your chest;
- CT or MRI scan within the previous six-months, which will be done to show the exact location and size of your pulmonary veins (the veins that return blood into the upper left chamber of your heart).
- If you are a female who is able to become pregnant, you will be asked to have a serum pregnancy test (a blood test.) If you are pregnant, you will not qualify for a routine ablation procedure or qualify to participate in this study.

Pre-Procedure Medication Management:

- Blood thinning medication is recommended for three weeks before the ablation procedure (if this is not possible, a transesophageal echocardiogram, which is the insertion of a tube with a transducer down the food tube [esophagus] to a place behind the heart, or an intracardiac echocardiogram is recommended in the EP lab before the ablation procedure – to rule out the presence of a blood clot in the left atrium of the heart.)
- Class I and III antiarrhythmic medications (AADs), except for amiodarone, will be stopped before the ablation procedure, as ordered by your study doctor. Examples of Class I AADs are flecainide and propafenone, and an example of a Class III AAD is sotalol.

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The following will occur during the ablation procedure:

The study doctor will explain the usual method of performing an RF or cryoablation catheter ablation procedure with you before the procedure. The risks and benefits will also be reviewed and you will be asked to sign a separate hospital informed consent form before the procedure.

After the ablation of the pulmonary veins is completed, you will be randomized to either pulmonary vein isolation (PVI) alone (that is, no further ablation will be done) or to PVI plus ablation of the posterior left atrial wall (PLAW.) If you are randomized to the second group, the PLAW ablation procedure will be done at this point in the procedure.

At the completion of the procedure all catheters will be removed and you will stay in the hospital for a minimum of six hours after the procedure or you may be monitored overnight. Also, as part of routine care after any AF ablation, the study doctor will talk to you about possible anti-arrhythmic drugs you may need to take after hospital discharge and the need for blood-thinning medication, for about three months after the procedure.

Follow-Up

After the ablation procedure, you will have follow-up clinic visits at 3, 6 and 13 months. These visits will take about thirty minutes each and are done as part of standard care.

At the 3, 6 and 13 month visits you will wear an event monitor for 7-14 days; this monitor records your heart rhythm.

A repeat echocardiogram will be done at 4-6 months after the ablation procedure.

Blood thinners are usually recommended for three months after the procedure. After three months, the continued need for blood-thinning medication will be based on your risk for stroke. Your study doctor will discuss with you the best treatment plan; this is done as part of standard clinical care.

Information about you and your heart arrhythmia, atrial fibrillation, will be collected during these follow up visits and from the tests listed above. This information will be analyzed as part of this research study.

How long will the study last?

Participation in this study is expected to last for about 13 months. After your ablation procedure, you will have follow-up visits at 3, 6 and 13 months.

It is expected that about 120 patients will participate in this two-center study.

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What are the possible discomforts and risks?

The study doctor will review the risks and discomforts of standard PVI and PLAW atrial fibrillation catheter ablation procedures with you before the procedure. These risks are not specific to this research study.

Possible Complication or Side Effect	Possible Rate of Occurrence **Frequent: More than 1 in 10** **Probable: More than 1 in 100, but Less than 1 in 10** **Occasional: More than 1 in 1,000 but Less than 1 in 100** **Remote: More than 1 in 10,000 but Less than 1 in 1,000** **Improbable: Less than 1 in 10,000**
Discomfort at the site of venous access in the groin(s)	Frequent
Groin Hematoma (site of localized swelling due to blood)	Probable
Thrombus formation/stroke (blood clot in the heart that could cause a stroke)	Occasional
Pneumonia	Occasional
Bleeding	Occasional
Cardiac Perforation (hole in the wall of the heart) requiring drainage or surgery)	Remote
Pulmonary venous stenosis/occlusion (narrowing of one of the pulmonary veins)	Remote
Injury to adjacent structures (phrenic nerve, esophagus, lung, cardiac valves)	Remote
Vascular complications (pseudoaneurysm, AV fistula requiring surgical intervention)	Remote
Myocardial infarction (heart attack)	Remote
Sepsis (infection)	Remote
Anaphylaxis (severe, life threatening allergic reaction, usually to a medication)	Remote
Death	Remote
Congestive heart failure (usually fluid build-up in the lungs, abdomen or legs)	Occasional
Renal dysfunction (abnormal function of the kidneys)	Occasional
Transesophageal echocardiography risks include dental and esophageal injury	Remote
Radiation burns (related to the radiofrequency energy used during the ablation procedure)	Improbable

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In addition, there may be uncommon or previously unknown risks that might occur. You should report any problems to the research staff.

You are encouraged to ask any questions about the possible and/or known hazards of this study at any time. You will be asked to tell the study doctor about any possible side effects you might have at any time during the study.

What are the possible benefits to you or to others?

The ablation procedures used in the study may control your abnormal heart rhythm (atrial fibrillation), preventing future episodes. However, it is possible that you may not receive benefit from taking part in this study. The information that is learned from this study may benefit other people in the future with the same condition and who need an AF ablation procedure.

If you do not want to take part in this study, what other options are available to you?

One option is not to participate in the study. You do not have to be in this research study in order to have a catheter ablation procedure to treat your atrial fibrillation.

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

If you decide to take part in this study, your medical records and personal information will be kept private to the extent allowed by federal, state, and local law. No personal information about you, your illness, or your treatment will be made public.

With your approval, the information obtained from the study will be submitted to the Principal Investigator and research team at Mercy Medical Group, Cardiology, and Dignity Health Medical Foundation and others as listed on the attached "Authorization for Use or Disclosure of Protected Health Information for Research Form." A special code, a four number combination, will be used to identify your study information.

In order to verify study data, the Principal Investigator and the Institutional Review Board (IRB) will also have the right to review your medical records as they relate to this study. In addition, publication(s) using data collected during the study will not include your name or any information that can identify you.

If you receive medical care from a doctor other than your study doctor while taking part in this study, you will be asked to agree that your medical records will be made available for the collection of data related to this study.

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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.

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

As all parts of this study are part of standard care for an approved, catheter ablation procedure for the treatment of AF, you or your insurance company will be responsible for these costs.

Will you receive compensation (payment) for taking part in this study?

No payment will be made to you for taking part in this study.

What if you are injured because of the study?

If you are injured as a direct result of taking part in this study, medical treatment will be available to you at your expense. No other arrangement has been made for financial payments or other forms of compensation (such as lost wages, lost time or discomfort) for injuries. You do not waive any legal rights by signing this consent form.

During the study, if you experience any medical problems or illnesses from taking part in this study, please contact Dr. Aryana at 916-736-2323.

What are your rights if you decide to take part in this study?

Your signature on this consent form means that you have received information about this research study and that you agree to be a part of the study.

You may stop taking part in the study at any time without penalty or loss of benefits to which you are otherwise entitled. If you wish to stop taking part in this research study for any reason, you should contact the study doctor. A decision to withdraw or to not take part in the study will not affect the quality of medical care that you receive or affect your future medical care.

Your study doctor may decide to withdraw you from the study at any time without your consent. If it is felt to be in your best interest, or if the study is stopped, your doctor may withdraw you from this research.

You will be told of any important new information that is learned during the course of this research study that may affect your condition or your willingness to continue to take part in this study.

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Conflict of Interest

This is an investigator initiated study. There is no commercial sponsor for the study; for that reason there are no conflicts of interest for Mercy General Hospital, Dignity Health Medical Foundation or the Medical Clinic of Sacramento, Inc.

The Principal Investigator, who is responsible for the conduct of this study, and the Sub-Investigators have no conflicts of interest.

Who can you contact for study information?

If you have any questions about the study or taking part in this study, please contact Dr. Aryana at 916-736-2323.

Should you have any questions about your rights as a research participant, you may contact the Institutional Review Board at 916-851-2283, Research@DignityHealth.org or by writing: Dignity Health CA/NV Institutional Review Board, 3400 Data Drive, Rancho Cordova, CA 95670.

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CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Signing this form means that I voluntarily consent to take part in this study. I have read this consent that describes what the study is about and what will happen during the study. I have discussed the research, including the risks, with someone involved in the research (doctor, nurse or the research staff).

I will receive a signed copy of this consent, the California Experimental Subject's Bill of Rights, and Authorization For Use and/or Disclosure of Protected Health Information (HIPAA) Authorization form.

I understand that by signing this consent, I do not give up or waive any of my legal rights.

I VOLUNTARILY AGREE TO TAKE PART IN THIS STUDY WHICH HAS BEEN EXPLAINED TO ME, AND ALL OF MY QUESTIONS HAVE BEEN ANSWERED TO MY SATISFACTION

Participant's Name _____ Date _____

Signature _____

(Date must be written in by the participant)

I discussed this study with the above named participant. This person had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participate in this study.

Person Obtaining Consent

Name _____ Date _____

Signature _____

(Date must be written in by the person obtaining consent)

Name of Investigator _____ Date _____

Signature of Investigator _____

(Date must be written in by the Investigator)

AUTHORIZATION FOR USE OR DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH (California)

PURPOSE: The sponsors and investigators of this study need to ask your *written* permission to use the information we learn about you in this study. This authorization is to obtain your permission to collect, use, release and/or disclose protected health information about you in connection with your participation in this study.

You do not have to sign this form but must do so if you wish to be part of this study. If you do not sign, you can still receive health care that is not related to this study.

Name of Subject:	Date of Birth:
Other Names (a.k.a)	M.R. or Account Number

NAME OF STUDY: Left Atrial Posterior Wall Isolation in Conjunction with Pulmonary Vein Isolation for Treatment of Persistent Atrial Fibrillation (PIVoTAL) Trial

STUDY SPONSOR NAME: **None**

GOAL OF STUDY: The purpose of this study is to learn if ablation of the posterior left atrial wall (PLAW) along with pulmonary vein isolation (PVI) will reduce the chance of atrial fibrillation recurrence one year after an ablation in comparison to a PVI ablation procedure alone.

PRINCIPAL INVESTIGATOR'S NAME: **Arash Aryana, MD**
3941 J Street, Ste. 350
Sacramento, CA 95819

WHO CAN DISCLOSE YOUR HEALTH INFORMATION?

- DIGNITY HEALTH and its facilities and clinics
- The Principal Investigator and the research team
- People providing care to you during this research

WHAT TYPES OF HEALTH INFORMATION ABOUT YOU WILL BE USED OR DISCLOSED IN THE STUDY?

- Consultation Reports
- Discharge Summary
- Emergency Room Reports / Records
- History & Physical
- HIV/AIDS information*

  *(**Note**: Researchers will not receive any HIV/AIDS test results but your medical record may include general information concerning your HIV status)
- Laboratory Tests
- Procedure Reports
- Progress Notes
- Radiology (X-ray, CT, MRI, etc.) Results
- Echocardiogram Reports
- Event Monitor Reports

WHO MAY RECEIVE AND USE YOUR HEALTH INFORMATION?

- Principal Investigator (listed above) and all research team members currently approved by the DIGNITY HEALTH IRB.
- The DIGNITY HEALTH Human Research Oversight Committee
- The DIGNITY HEALTH Institutional Review Board(s) and Medical Staff Departments which provide oversight of this study.
- The U.S. Food and Drug Administration (FDA) and Department of Health and Human Services (DHHS) agencies.

IRB NUMBER: SAC-2016-257
IRB APPROVAL DATE: 02/04/2017

CAN YOU CHANGE YOUR MIND OR REVOKE YOUR AUTHORIZATION?

You may withdraw (cancel) your permission for the use and/or disclosure of information about you for this Study, but you must do so by notifying the Principal Investigator (listed above) in writing. All information collected before receiving your written withdrawal, including your reasons for stopping your participation in this research study, may still be used by the Principal Investigator and other parties subject to this authorization as permitted by law. If medically indicated, the Principal Investigator or study staff may ask to follow-up with you for safety reasons. If you withdraw your authorization for the use and disclosure of your health information for this Study, the follow-up information cannot be used or disclosed for this Study, except if required or permitted by law.

WILL YOUR HEALTH INFORMATION BE USED IN OTHER STUDIES?

No. This form authorizes DIGNITY HEALTH to release your health information to the study sponsor and investigators for this research only. However, once your health information is released outside DIGNITY HEALTH it may not be protected by the privacy laws and might be shared with others. Please read the study consent form carefully before signing this authorization.

WILL YOU HAVE ACCESS TO YOUR HEALTH INFORMATION (Medical Records) DURING THE RESEARCH?

- No. Your ability to access protected health information about you (like reading, changing or copying your medical records) will be limited for a certain time as noted below, but only if your access would otherwise interfere with study procedures. You may choose not to participate in the Study if you want to have full access to your health information. You will have full access to your records when the study is finished.
    - No access during the 13 months of participation in the study.

HOW LONG IS THIS AUTHORIZATION EFFECTIVE?

This authorization to use or disclose protected health information about you will automatically expire one year from the date you sign this form, unless a different end date is specified here: **December 31, 2028**.

IRB NUMBER: SAC-2016-257
IRB APPROVAL DATE: 02/04/2017

AUTHORIZATION AND ACCEPTANCE

By signing below, you are saying that you have read this form and agree to permit the use and disclosure of health information about you as described in this form. You will be given a signed copy of this authorization form for your records.

Name of Subject (Please Print)	Date:
Subject Signature:	

If you have any questions about permitting the use and disclosure of your health information or about being part of this study in general please contact the principal investigator or DIGNITY HEALTH Institutional Review Board (IRB) that has approved this project.

Principal Investigator: **Arash Aryana, MD**	**Phone:** **916-736-2323**
DIGNITY HEALTH Sacramento Regional Institutional Review Board:	**Phone:** **916-851-2193**

IRB NUMBER: SAC-2016-257
IRB APPROVAL DATE: 02/04/2017

Note: **AIDS related information** may only be disclosed to the recipients identified in the Authorization provided the following statement prohibiting re-disclosure is provided to the recipient of the information (Cal. Health & Saf. Code §121080)

NOTICE TO RECIPIENT OF

PHI RELATING TO ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

This information has been disclosed to you from a confidential research record, the confidentiality of which is protected by California law and any further disclosure of it without the specific prior written consent of the person to whom it pertains is prohibited. Violation of these confidentiality guarantees may subject you to civil or criminal liabilities.

IRB NUMBER: SAC-2016-257
IRB APPROVAL DATE: 02/04/2017