BAYLOR SCOTT & WHITE RESEARCH INSTITUTE
Baylor Scott & White Health the Heart Hospital Plano
Plano, TX

CONSENT FORM AND PRIVACY AUTHORIZATION

PROJECT TITLE: Distal vs. Proximal Radial Artery Access for cardiac catheterization and intervention (The DIPRA Study)

PRINCIPAL INVESTIGATOR ("PI"): Karim Al-Azizi, MD

TELEPHONE NUMBER: 972-665-6100

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering taking part in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future. Taking part in this study is voluntary.

1. WHY HAVE I BEEN ASKED TO TAKE PART IN THIS STUDY?

You are being asked to take part in this research study because you may have disease or damage in the major vessels that supply blood and oxygen to your heart, and you are having a heart catheterization (insertion of a thin, hollow tube in your heart) in order to see or treat this disease. This can also be called a heart angiography or angioplasty. You and your doctor have decided that they will do this procedure via the artery in the wrist (radial artery).

2. WHY IS THIS STUDY BEING DONE AND HOW LONG WILL IT LAST?

The purpose of this study is to compare hand function following distal radial artery access compared to proximal artery access, in subjects like yourself that have a catheterization via the artery in the wrist. The doctor will either access the artery via the distal side (the hand), or the proximal side (the wrist). This will be decided randomly like the flip of a coin. The researchers also want to see if the radial artery remains unblocked up to one year after the procedure.

We think that you will be in the study for about one year after your heart catheterization procedure.

3. WHAT WILL I BE ASKED TO DO IN THIS STUDY?

You will have a heart catheterization and come to follow-up visits as instructed by your doctor, like you would if you weren't in the study. The procedures discussed below will be done because you are in the study.

Before the procedure you will:

- Have a Doppler ultrasound (using a portable ultrasound device) to make sure that the doctor can access your radial artery both distally and proximally.
- Take one questionnaire that asks you about your ability to do certain activities (DASH questionnaire).

- Complete tests that test the strength and function of your hands on both hands.
- Be randomized (randomly chosen like the flip of a coin) to decide where the doctor will access your radial artery. This will be either distally or proximally.

After the procedure you will:

- Have a Doppler ultrasound (using a portable ultrasound device) to see if your radial artery is open and not blocked at 1 month and 12 months.
- Repeat the tests that test the strength and function of your hands at 1 and 12 months after your procedure. You will also take the DASH questionnaire again at each of these visits.

By analyzing the results of these tests and questionnaires before and after the procedure, the researchers hope to see what happens to hand function due to accessing the artery at different places on the wrist.

4. WHY MIGHT I WANT TO TAKE PART IN THIS STUDY?

If you agree to take part in this study, there may not be direct medical benefit to you. We hope that the information learned from this study will benefit other subjects that need to have this procedure in the future.

5. WHY MIGHT I NOT WANT TO TAKE PART IN THIS STUDY?

The risks of taking part in the study are the same as the risks of having a heart catheterization outside the study. The risks associated with this procedure will be explained to you in detail during your clinic appointment and before you have the procedure. You will be asked to sign a consent form to have the procedure at that time. The procedures you are doing because you are in the study are safe. There are no risks for answering the questionnaires and you may feel discomfort during the hand function tests. There is no known risk of having a Doppler ultrasound.

The researchers do not know all of the side effects that could happen. For a complete description of known risks, refer to the Detailed Information section of the consent form.

6. WHAT OTHER OPTIONS ARE THERE?

- You may choose not to take part in this study.
- You may choose to receive a heart catheterization without taking part in the study.

Please talk to your regular doctor about these and other options.

7. HOW WILL TAKING PART IN THE STUDY AFFECT ME FINANCIALLY?

There is no additional cost to you if you take part in this study. You will not be paid for taking part in this study.

What is the Status of the Procedures Involved in This Study?

All the procedures performed in this study are routinely performed, in the U.S. and worldwide. The distal radial artery approach is relatively new and according to our experience and published reports, it is safe and comfortable.

How Many People Will Take Part In This Study?

About 300 people will take part in this study at Baylor Scott & White Health the Heart Hospital Plano (THHBP).

What Will I Be Asked To Do?

We will need to collect your general medical history, including the medicines you take, the results from blood tests collected as part of your routine health care, and any baseline heart exams that you have already had. The risks associated with heart catheterization will be explained to you in detail during your clinic appointment and before you have the procedure. You will be asked to sign a consent form to have the procedure at that time.

You will have the heart catheterization and come to follow-up visits as instructed by your doctor, like you would if you weren't in the study. You will be asked about your pain level before and after the procedure.

The procedures below will be done because you are in the study.

Before the procedure you will:

- Have a Doppler ultrasound (using a portable ultrasound device) to make sure that your doctor can access your radial artery (major artery that is located on the underside of the forearm) both distally (near base of thumb) and proximally (underside of wrist). You will not be able to be in the study if the doctor cannot access your radial artery.
- Take one questionnaire that asks you about your ability to do certain activities (DASH questionnaire). It will take about 5-10 minutes to complete this questionnaire.
- Have hand function tests on both hands. This includes the "pinch grip" test and the "hand grip" test. The pinch grip requires you to grasp an object with the thumb on one side and the rest of the fingers on the other side. The hand grip test requires you to grasp an object with your hand and it measures your strength when you make a fist. These tests will take about 10-15 minutes to complete.

After the procedure you will:

- Have a Doppler ultrasound (using a portable ultrasound device) at 1 month and 12 months after your procedure, to see if your artery is open or blocked.
- Repeat the pinch grip and hand grip tests on both hands at the outpatient visits at 1 and 12 months after your procedure. This will take about 10-15 minutes to complete each time. You will also take the DASH questionnaire. It will take about 5-10 minutes to complete this questionnaire.

Other than the questionnaires, the hand function tests, and the Doppler Ultrasounds, your care is the same as it would be even if you weren't taking part in this research study. Here is a summary of the procedures required for this research study:

	Screening	Heart Procedure	1 Month Visit	12 Month Visit
Informed Consent	X			
Portable Ultrasound	X		X	X
Questionnaire		X	X	X
Hand Function Tests		X	X	X

Your Responsibilities as a Research Subject:

Commitment: While you always have the right to change your mind and leave this study, you should enter this study only if you think you will want to be in it until it ends.

Visits: You agree to come for all study visits and to follow the instructions of the research doctor/staff, even if you stop the study medicine. In case it is not possible for you to attend a visit, we will contact you by phone or mail.

Problems: You will let the research doctor/staff know immediately if any problems occur while you are involved in this study. You will also let the research doctor/staff know if you have to go to an emergency room, doctor's office, or a hospital.

Medicines: You will let the research doctor/staff know about any changes in your prescription medicines, over-the-counter medicines, and all vitamins or supplements that you take, and will keep all study medicine and/or supplies out of the reach of others.

Women of child-bearing potential: You will let the research doctor/staff know immediately if you miss a period or think you may be pregnant.

Other studies*:* You will not take part in any other study at the same time you are in this study (unless you are given permission by both PI's).

How Long Will I Be In This Study?

You will be in this study for about one year following your heart catheterization procedure. You will be required to come in for research visits at 1 month and 12 months after your procedure. In most cases, these visits will be on the same day as your routine outpatient visits to your doctor.

The researcher may decide to take you off this study if any of the following occur:

- He/She feels that it is in your medical best interest.
- Your condition worsens.
- New information becomes available.
- This study is stopped by the sponsor.

You can stop taking part in this study at any time. However, if you decide to stop taking part in this study, we encourage you to talk to the researcher and your regular doctor first.

It is very important in clinical trials to know if subjects are alive and well by the end of the clinical trial. To do this, we ask the following things:

- ***Location and telephone number updates:*** At each visit, our staff will ask you if any of your contact information has changed. Please let us know of any changes at any time.
- ***Closest Relative or Friend:*** Please provide us with the name of a relative or friend whom we can contact in the event that you cannot make visits and we cannot reach you. We want to be able to ask this person information about your health status.
- ***Doctor:*** If we cannot reach you or one of the people you have listed above, we will contact your doctor to find out about your health.
- ***Public Registries:*** If you drop out of this study and we are unable to contact anyone with information about your health status, we will search Public Registries (such as the US Postal Service, Social Security, and social media) for information about you.
- ***Minimum information:*** We will not disclose any of your personally identifiable health information beyond the minimum required to confirm your health status.

What Are The Risks of This Study?

While on this study, you are at risk for these reactions, sometimes bad, which are listed below. You should discuss these with the researcher and/or your regular doctor. There also may be other reactions that we cannot predict. These unknown reactions could also be to your unborn child if you are pregnant or become pregnant while on this study. Other medicines may be given to make them less serious and uncomfortable. Many of these reactions go away shortly after the the procedure is complete, but in some cases, they can be serious or long lasting and permanent .

Risks and reactions related to the heart catheterization via the wrist include:

- A blockage forms in the artery (artery occlusion)
- Bleeding
- Damage to hand function, possibly permanent: We do not know if this technique has negative effect on hand function, but based on the structure of the hand and wrist we do not expect a negative outcome. This is exactly what we want to show with this study.

These are the same risks you would experience without taking part in this study.

There are no risks associated with questionnaires taken in this study. There may be possible physical discomfort performing the hand function tests. There are no known risks for having a Doppler Ultrasound.

Reproductive Risks: Because the procedures and drugs in this study could harm an unborn baby, you should not become pregnant while on this study. You should not nurse your baby while in this study. Ask about counseling and more information about preventing pregnancy.

Conflict of Interest

Your doctor may be an investigator in this study. If so, he is interested both in your medical care and in the conduct of this research. Before you sign up for this study or at any time during the research, you may discuss your care with another doctor who is not associated with this research project. You are not under any obligation to take part in any research study offered by your doctor.

The people working on this study may be paid for their work on this research study from money provided by the company sponsoring this research study. The people working on this study may be paid for other work that is unrelated to this study, such as consulting with the sponsor company or speaking at educational programs at the request of the sponsor company or other companies that may have an interest in this study.

What About Confidentiality?

You have a right to privacy. This means that all the information about you from this study will only be shown to the people working on this study. The results of this study may be published in a scientific book or journal. If this is done, your name will not be used. All information about you from this research project will be kept in a locked office or other locked area. Information that is kept on computers will be kept safe from access by people who should not see it.

The privacy law requires that Baylor Scott & White Research Institute ("BSWRI") and your doctors and other health care providers and facilities that have provided services to you, which could include doctors that work for the Scott & White Clinic, HealthTexas Provider Network or Texas Oncology, P.A., Baylor University Medical Center, Scott & White Medical Center – Temple and other health care providers depending on where you have received care (collectively, "Your Health Care Providers") get your permission before giving any of your health information to other people. There are people who need to review your information to make sure this study is done correctly. These people may look at or copy your information while they are doing this review. When you sign this form you give permission to BSWRI and Your Health Care Providers to give other people information about your health as needed for the research project. These groups include people who work for BSWRI (including the Institutional Review Board), Baylor Scott and White Health, Baylor Scott & White Dallas Foundation, the US Food and Drug Administration, the Office for Human Research Protections and the Association for the Accreditation of Human Research Protection Programs. Even though we usually remove your name from the information, the people who get this information may be able to figure out who you are. The kinds of health information that might be given to these people include results from lab tests or other tests like the hand function test results or your answers to the questionnaires. This information might also include notes and other information in your medical records. We may ask for these notes and other information in your medical records from Your Health Care Providers. This means that the records of your care and information about you maintained by Your Health Care Providers may be given to the people mentioned above and, by signing this form, you are agreeing that Your Health Care Providers may release this information to these people.

You do not have to give this permission and it is all right to refuse to sign this form. Your doctor will still treat you and your insurance company will still pay your medical bills (according to their policy) even if you do not give your permission for BSWRI and Your Health Care Providers to release this information. However, since it is important for the people listed above to have access to your information, if you do not sign this form, you cannot be in this study.

If you give permission to BSWRI and Your Health Care Providers to give other people information about your health and the other people are not part of the group that must obey the privacy law, your health information will no longer be protected by the privacy law. However, we will take all reasonable measures to protect your information from being misused.

If you change your mind and later want to withdraw your permission, you may do so. You must notify BSWRI in writing at 2001 Bryan St, Suite 2200, Dallas, TX 75201. Please be sure to tell us the name of this study and the PI for this study for which you are withdrawing your permission. BSWRI will provide your withdrawal notice to Your Health Care Providers promptly after BSWRI receives your withdrawal notice. While not required, you should also talk to your PI and Your Health Care Providers and make sure they are aware you are withdrawing your permission. If you withdraw your permission, it will not apply to information that was given to others by BSWRI before you withdrew or to information given to others by Your Health Care Providers before Your Health Care Providers receive your notice withdrawing your permission. If you withdraw your permission, you will no longer be able to take part in this study.

You may not be allowed to look at your study-related health information during this study. However, at a later time, you will be able to look at this information. This later time will be sometime after this study is completed.

Unless permission is withdrawn, this permission will not expire at the end of this study.

A description of this clinical trial will be available on 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 Financial Information

You or your insurance company will pay for all charges related to the heart catheterization procedure and the follow-up visits. You would need to pay for this even if you were not in the study. The sponsor of the study, Baylor Scott & White Dallas Foundation, will pay for the following procedures that are only done because you are in the study:

- The time and effort it takes personnel to collect the answers to your questionnaires, and to perform the hand strength tests and the Doppler ultrasound.

This means, there will be no cost to you for being in this study. If you see the same doctors for other clinical care, you or your insurance company will be responsible for those costs, the same as if you were not in the study.

Taking part in the study may lead to added costs to you or your insurance company. Someone within the billing department will work with you to get any pre-approvals necessary and inform you of any charges that you will need to pay. Your insurance company may ask for us to provide them a copy of this consent form. Charges for tests and examinations done as part of a research study may not be covered by your health insurance company (including Medicare). You will be responsible for all deductibles, co-pays and other charges not paid by your insurance company.

You will not be paid for being in this study

What if I am Injured or Become Ill While Taking part in this Study?

The people doing this research project will do everything they can to make sure you do not get hurt during the project. If you do get hurt, there are some things that you need to know:

- Baylor Scott and White Health, Baylor Scott and White Research Institute and Baylor Scott & White the Heart Hospital Plano have not set funds aside to pay you money if you are hurt.
- Baylor Scott & White Dallas Foundation has not set funds aside to pay you money if you are hurt.
- If you have an emergency illness during the project, the people working with you will provide emergency care. You or your insurance company may need to pay for the emergency care if that happens.
- You have not given up any of your legal rights by signing this form.

The Centers for Medicare and Medicaid Services (CMS), the agency that administers the Medicare program, has stated that payments by clinical trial sponsors for injuries related to a trial are a form of liability insurance and must be reported to CMS. As a result, if Baylor Scott & White Dallas Foundation pays any medical expenses to treat a trial-related injury, and if you are covered by Medicare, Baylor Scott & White Dallas Foundation must report that payment to CMS. In order to do that, Baylor Scott & White Dallas Foundation must have certain individually identifiable information about you, such as your name, date of birth, Social Security number, Medicare claim number, date of injury and a description of the injury.

While Baylor Scott & White Dallas Foundation normally will not receive any individually identifiable information about you, Baylor Scott & White Dallas Foundation (or its delegate) will receive your individually identifiable information if (and only if) you are covered by Medicare and have incurred medical expenses that have been determined to be the result of a trial-related injury. If it receives your individually identifiable information, Baylor Scott & White Dallas Foundation (or its delegate) will only use that information to make legally required reports to CMS.

What are My Rights As a Subject?

Taking part in this study is voluntary. You may choose not to take part or may leave this study at any time. If you agree to take part and then decide against it, you can withdraw for any reason. At certain times during the treatment, it may be unsafe for you to withdraw, so please be sure to discuss leaving this study with the PI or your regular doctor. Deciding not to be in this study, or leaving this study early, will not result in any penalty or loss of benefits that you would otherwise receive.

We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

Whom Do I Call If I have Questions or Problems?

If you have concerns, complaints or questions about this study or have a research-related injury, contact Dr. Karim Al-Azizi at 972-665-6100.

For concerns, complaints or questions about your rights as a research subject or if you simply wish to speak with someone who is not a part of the research staff, contact the IRB Office at 214-820-2687 (North Texas IRB Office).

Primary Care Doctor

Please indicate below whether you want us to notify your primary care doctor or your specialist of your taking part in this study.

_____ Yes, I want the study doctor to inform my primary care doctor/specialist of my taking part in this study.

_____ No, I do not want the study doctor to inform my primary care doctor/specialist of my taking part in this study.

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

____ The study doctor is my primary care doctor/specialist.

PERMISSION TO OBTAIN INFORMATION FROM ADDITIONAL SOURCES

If the study site is unable to contact me after repeated attempts at any point during the study, I authorize the study site to contact my personal doctor and family member or friend to obtain information about how to contact me and to learn about changes in my health. I also authorize the site to use public records to find information that can help them to contact me.

Name of personal doctor: _____
Phone number: _____

Name of friend/family member:_____
Phone number: _____
Relationship: _____

___ I do not wish to provide this information or allow these methods to be used to contact me.

Statement of Person Obtaining Consent:

I have explained to _____(printed name of subject and parent/legal representative if applicable) the purpose of this study, the procedures required and the possible risks and benefits to the best of my ability. They have been encouraged to ask questions related to taking part in this study. I gave a copy of this consent to the subject.

_____ _____ _____
Signature of Person Obtaining Consent Date Time

Confirmation of Consent by Research Subject:

You are making a decision about being in this study. You will be asked to give your written consent if you want to be in this study. Giving consent is like giving permission. You should not give your permission to be in this study until you have read and understood all pages in this form. Make sure that all your questions about this study have been answered before you sign this form. When you sign this form, you are giving your permission to be in the study. By signing this form, you have not given up any of your legal rights or released anyone from liability for negligence.

_____ (printed name of person obtaining informed consent) has explained to me the purpose of this study, the study procedures that I will have, and the possible risks and discomforts that may happen. I have read (or have been read) this consent form. I have been given a chance to ask questions about this study and the procedures involved. I believe that I have enough information to make my decision. I have also been told my other options. To the best of my knowledge, I am not in any other medical research. Therefore, I consent to take part as a subject in this study and authorize the activities described in this consent. I also acknowledge that I have received a copy of this consent form.

_____ _____ _____
Signature of Subject Date Time