DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
Prospective Multi-center Imaging Study for Evaluation of Chest Pain (PROMISE)

You are being asked to take part in this research study because you have symptoms which may be from heart disease but you have no previous history of heart disease. Before agreeing to participate in this research study, it is important that you read and understand the information provided. Research studies are voluntary and include only those who choose to take part. This consent form describes the purpose, procedures, benefits, risks, discomforts and alternative treatments that are available to you, as well as your right to withdraw from the study at any time. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of ***(insert your PI's Name here)*** and his/her research team's salaries will be paid by this grant.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, ***Dr.*** _____ will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to compare different, routinely performed heart tests, such as exercise treadmill testing, stress echocardiogram, cardiac nuclear imaging, and coronary computed tomography angiography (CTA), in identifying heart disease and reducing future heart problems.

Your participation in this research study is voluntary.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
The study will be conducted at about 200-250 different hospitals and medical facilities. About 10,000 people will take part in this study, and up to 1000 people could take part here at **[INSERT INSTITUTION/FACILITY NAME]**

WHAT IS INVOLVED IN THE STUDY?
Your doctor has already determined that you need a heart test to understand the cause of your symptoms. The results of this test will help your doctor determine what type of treatment you will need for your symptoms.

If you agree to be in this study, you will be asked to sign this consent form. A baseline visit will take place after you sign. During this visit, information will be collected about your medical history and what medications you are taking. You may also have a brief physical examination. You may need to have about 8mls of blood (about one and a half teaspoons) drawn if your creatinine values (a measure of how your kidneys are working) have not recently been drawn. If you are a woman capable of having children,

you will need to have a negative pregnancy test prior to participating. From the time you have your pregnancy test until you have your assigned heart test, you must use a medically acceptable form of birth control. Medically acceptable contraceptives include: (1) surgical sterilization (such as a tubal ligation or hysterectomy), (2) approved hormonal contraceptives (such as birth control pills, patches, implants or injections), (3) barrier methods (such as a condom or diaphragm) used with a spermicide, or (4) an intrauterine device (IUD). Contraceptive measures such as Plan B(TM), sold for emergency use after unprotected sex, are not acceptable methods for routine use.

If you are allergic to iodinated contrast agent (a liquid injected in your veins to allow the physician to obtain clearer images of your heart) you will not be able to participate in the trial.

The staff of **[INSERT INSTITUTION/FACILITY NAME]** will also ask you questions about your health and any heart symptoms you may be having, about your physical and social activities, how you are feeling emotionally, and some questions about your work status and education. These questions are part of the research study and will take about 20 minutes to answer. You may refuse to answer any of the questions.

You will be asked to fill out a Confidential Patient Information (contact) form in order for representatives from the **[INSERT INSTITUTION/FACILITY NAME]** and/or the Duke Clinical Research Institute Outcomes and Follow-up Group (Follow-up Group) to contact you to collect follow-up information. This form will ask specific information such as your name, address, phone numbers of family members or close friends whom you designate to respond to the follow-up questions in the event that you are unable to do so. This contact information will only be available to **[INSERT INSTITUTION/FACILITY NAME]** and the Follow-up Group. Your agreement to share this information with us will not affect your care in any way.

You will be randomly assigned (like a flip of a coin) to one of two study groups. In order to assign you to one of these two groups, an automated voice system will be called and information such as your date of birth and gender will be entered.

If you are assigned to the first group, you will receive a heart test to look at how your heart functions when it is working hard. The exact test will be chosen by your current doctor – exercise ECG, stress echo, or stress nuclear test. The choice will be based on your medical condition, test availability, and doctor preference. This is the test you would have received, regardless of your participation in this study. A brief description of each test is noted below. You will receive more details about your chosen test prior to starting the test.

☐ Exercise ECG: You will have patches put on your chest for an electrocardiogram. A technician will take your blood pressure and an ECG at rest. You will then walk slowly on a treadmill. Gradually, the speed and the incline of the treadmill will increase to allow you to walk faster and simulate walking up a hill. During the test, your ECG will be watched and recorded, and every few minutes a blood pressure will be taken. The test will stop when you reach a target heart rate or you have symptoms that do not allow you to keep going. Your ECG and blood pressure will be monitored for 10-15 minutes after while

you rest. The recordings and blood pressures will be looked at by a doctor to understand how your heart works during exercise.

☐ Stress Echo: This test uses sound waves to look at your heart. You will be asked to lie on an exam table and patches will be put on your chest for an electrocardiogram (ECG). A technician will put gel on your chest and move a small instrument around on your chest. The technician will view your beating heart on a screen, and make a recording of the pictures and your ECG. You will then exercise (on a treadmill or cycle) or be given a medication, based on your doctor's preference, to make your heart beat faster. When your heart is beating faster, you will then lay back down on the table to complete another echocardiogram as described above. The recordings will be looked at by a doctor to understand how your heart works.

☐ Stress Nuclear: A small amount of "tracer" (a radioactive drug that allows your blood to be seen by a special camera) is injected into your vein. You will be asked to lie on a table under a special camera that takes pictures (or scans) of your heart's blood flow. You will then exercise (on a treadmill or cycle) or be given a medication, based on your doctor's preference, to make your heart beat faster. When your heart is beating fast enough, a small amount of tracer will be injected into your vein again, and you will lie on the table and complete another nuclear scan test as described above. The scans will be looked at by a doctor to understand how your heart works.

If you are assigned to the second group, you will receive a Coronary Computed Tomography (CT) Angiography. Pictures of your heart will be taken, including pictures of the arteries to look for blockages. CT is a way to make x-ray images of the inside of the body. The CT scanner is a doughnut-shaped machine that uses x-rays to create computer pictures that show structures inside your body more clearly than regular x-ray pictures. During the procedure, a technologist will take you into the CT scan room where you will lie down on the patient table (usually on your back) inside of the CT machine. You should get comfortable because it is very important that you not move during certain parts of the test.

Since the CT examinations would be of your heart, a series of pictures will be taken from your lower chest to your upper chest/neck. During the study, you will be asked to hold your breath so that the pictures will not be blurred. The machine will make some noise, and the table will move during the scan. Also, you may receive signals from the technologist or from the machine about your breathing. Before or during the study, you may be given an injection of a contrast liquid in your vein to allow the radiologist to obtain clearer images of your heart. If you have any discomfort during the test or after the injection, be sure to tell the technologist.

As part of the study, Dr. **[INSERT PI NAME]** and **[his/her]** study team will report the results of your laboratory tests and heart tests to the DCRI and the American College of Radiology Imaging Network (ACRIN) regardless of which heart test you receive. ACRIN is the central agency that will receive and store the exam results/pictures from all study participants in this study. Your exam results/pictures will be identified by a unique study code number and time assigned when you enter the study along with your year of birth and test date and time. Your exam results/pictures will be securely stored by ACRIN forever

and may be used in the future for secondary studies and research. No individual names or results that could identify you personally will be used. Your exam results/pictures may also be sent by ACRIN to the diagnostic testing core labs for further review, to evaluate standard testing procedures.

Depending on which heart test you receive, your exam results/pictures may also be shared with the Exercise ECG Core Lab, the Stress Echocardiogram Core Lab, the Stress Nuclear Core Lab or the Computed Tomography Angiography Core Lab. Identifying information will be removed (except for your unique study code number, year of birth and test date and time) from your exam results/pictures before it is shared with these labs.

Approximately sixty days after you are enrolled in this study, you will either have a follow-up visit with your doctor's study staff, or you will receive a telephone call from your doctor's study staff. During this visit or call you will be asked if you have had any heart symptoms, heart procedures or hospitalizations since your last visit and what medications you are taking.

After you are enrolled in the study, representatives of the Follow-up Group will contact you by telephone, mail or email at six months, 12 months and every 6 months until the conclusion of the study to ask if you have had any heart symptoms, heart procedures or hospitalizations, and what medications you are taking. In addition, at 6 months and once per year until the end of this study, you will be contacted and asked questions about how you are doing and any changes in how you may feel or in your ability to perform daily activities or in your working status. The Follow-up Group may contact family /friends identified by you as alternate contacts in the event that they are unable to reach you directly

Additionally, the Follow-up Group may request permission to contact your doctor(s) or hospital(s) to obtain copies of your medical records, tests and bills throughout the course of the study. This information will be used to determine the cost effects of the diagnostic testing being studied in this research trial. All information obtained will be kept confidential and no identifying information will be shared outside the study follow-up team and your health care providers. At the conclusion of the study your contact information will be destroyed. By signing this form, you authorize this access.

BIOMARKERS AND GENOMICS BIOREPOSITORY

A "biorepository" has been developed as part of this research study. Your participation in this part of the study is optional and does not impact your participation in the main part of the study. A "biorepository" is a collection of stored blood plasma (the liquid containing proteins that remain after removal of blood cells) and serum (the liquid remaining after the blood's clotting factors have been removed) samples and information, including genetic material. Researchers may study the stored materials in the future. Through such studies, they may find new ways to detect, treat, and maybe prevent or cure health problems. Some of the studies may lead to new products, such as drugs or tests for diseases.

Plasma and serum from blood contain many substances, some of which are called "biomarkers". Biomarkers may provide important information about how cardiovascular disease begins and progresses. These biomarkers may also predict how a patient will respond to a treatment. Some examples of biomarkers in your blood are cholesterol, vitamin D, and stress hormones like cortisol.

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Genomics is the study of your genes and how they work. Genes hold the instructions to build and maintain your cells. Your cells contain two types of genes. One type contains the instructions and is called deoxyribonucleic acid (DNA). The second type translates the DNA for the cell and is called ribonucleic acid (RNA). Differences in genes between people may predict who is at risk for disease. The more that is learned about these differences in genes and how they work may help to improve our understanding and treatment of patients.

If you choose to participate in the biomarkers or genomic parts of the biorepository study, up to 50 mls (about 3 tablespoons) of blood will be drawn (ideally at your first study visit) from a vein in your arm by needlestick. The blood will be processed and shipped to Esoterix Clinical Trial Services/Laboratory Corporation of America for cataloging and storage. The samples will be kept indefinitely (banked) and will only be identified by a number or code to protect your privacy. All samples will be owned by the National Heart Lung and Blood Institute, the sponsor of this study. Results from this research use of your samples will not be used to evaluate your medical condition or provide you with additional treatment. You will not have access to your sample or any information obtained from the study of these samples.

Special precautions have been taken to ensure that this research is done with the highest level of confidentiality. After DNA and RNA is extracted (taken) from the blood, a new code will be assigned to your DNA and RNA samples and to any results linked to your DNA and RNA. This new code provides an additional level of security. The only link between you and the code assigned for your DNA and RNA will be maintained by an independent authority and kept in a secure environment with restricted access. This link will be destroyed before the DNA and RNA testing is conducted. You will only be able to withdraw your sample prior to that time. If you provide written withdrawal within this time (as described below), the researchers will take the necessary steps to destroy your sample. However, if genomic or biomarker testing has already been done, it will not be possible to identify your samples and destroy them.

Risks of Genomics: The risks specific for Genomics are the possible discovery of a new medical condition for the patient or the potential loss of privacy

Storing your blood, DNA, and RNA for future research is optional. There is no cost to you for storage of your sample and you will not be compensated for providing a sample. To participate in the genomics part of the study you must agree to the following:

- to allow your anonymized samples to be tested for factors, including genes, related to your condition or related conditions
- to allow your anonymized samples to be stored for future use by researchers studying all diseases
- to allow researchers from private companies or other qualified institutions to have access to your anonymized blood samples, DNA, RNA, and genetic data, which may be used to develop diagnostic lab tests or pharmaceutical therapies that could benefit many people
- to allow anonymous information about you to be included in a data set that is available to qualified researchers outside the study

- to allow researchers to conduct future studies using your anonymous samples without asking for your additional consent

If your blood, DNA, or RNA is shared with other researchers, they will not be able to identify you.

The National Institutes of Health (NIH) has established a national database that will hold information from many individuals across the country, including medical information and genetic information. Your blood contains genes which are made of DNA that is unique to you. If coded information about you is sent to this national database, access will be controlled and limited to other researchers.

A Federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

I understand that giving my blood for future research is optional:

BIOMARKERS

☐ **I AGREE** to have my samples stored for future **biomarker** research (initial here)_____

OR

☐ **I DO NOT AGREE** to have my samples stored for future **biomarker** research (initial here):

_____

GENOMICS

☐ **I AGREE** to have my samples stored for future **genomic** research (initial here): _____

☐ **I DO NOT AGREE** to have my samples stored for future **genomic** research (initial here): _____

HOW LONG WILL I BE IN THIS STUDY?

The entire study will last approximately 5-6 years. The duration of your participation will be a minimum of 2 years and up to 6 years, depending on when you are enrolled.
You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

WHAT ARE THE RISKS OF THE STUDY?

There are several potential risks with this study, some of which may be unforeseen. There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential, however, this can not be guaranteed. Some of the questions we will ask you as part of this study may

make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

You will be informed in a timely manner if new information becomes available that may affect your willingness to continue participation in this study.

Risks Unique to the Study - the following risks are uniquely related to participation in this study.

Risks of Drawing Blood: Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting is also possible, although unlikely.

Risks of CTA: Risks associated with CTA are radiation (see below), use of certain drugs to lower heart rate during your procedure, and the use of a contrast liquid to allow the radiologist to obtain clearer images of your heart. The risk of contrast liquid includes allergic reaction (itching, hives, wheezing, difficult breathing, swelling of the larynx, drop in blood pressure and loss of consciousness), seizures, irregular beating of the heart and kidney problems.

Risks Associated with Routine Heart Testing - the risks noted below that pertain to the heart testing are the same whether you are in the study, or if you and your doctor choose to perform these tests as part of the typical care for your symptoms. Participation in this study does not increase these risks.

Risks of Radiation: If you take part in this research, you will have one or more medical imaging studies which use radiation. The tests or treatments you will have include a cardiac computed tomography (CT) angiography or cardiac nuclear imaging. Everyone receives a small amount of unavoidable radiation each year. Some of this radiation comes from space and some from naturally-occurring radioactive forms of water and minerals. This research gives your body the equivalent of about 4 extra years' worth of this natural radiation. The radiation dose we have discussed is what you will receive from this study only and does not include any exposure you may have received or will receive from other tests.

Risks of Cardiopulmonary Exercise Testing: During the exercise test you may become short of breath and tired, but you will be allowed to rest. You may be given medicine to help your breathing improve if this occurs. The testing involves rare but significant risks of heart attack, fast dangerous beating patterns of the heart, stroke or artery clot, and death.

Risks of Echocardiogram**:** The person performing the test will press on your chest with a machine to obtain the pictures. Rarely, the pressure can be uncomfortable.

Risk of Stress Nuclear testing: It is possible you could be allergic to the radioactive dye that's injected into your vein in order for the physician to see the blood flow to your heart both at rest and during stress. Allergic reaction includes itching, hives, wheezing, difficult breathing, swelling of the larynx, drop in blood pressure and loss of consciousness.

If you experience any of these side effects, the sponsor or the Duke Clinical Research Institute (DCRI) may need to review your entire medical record.

Women of Childbearing Potential (if applicable)

Being a part of this study while pregnant may expose the unborn child to significant risks if you are assigned to receive the Coronary CTA or Stress Nuclear Testing. If you are a woman capable of having children, you must have a negative pregnancy test prior to participating in this study. From the time you have your pregnancy test until you have your assigned heart test, you must use an acceptable form of birth control. Medically acceptable contraceptives include: (1) surgical sterilization (such as a tubal ligation or hysterectomy), (2) approved hormonal contraceptives (such as birth control pills, patches, implants or injections), (3) barrier methods (such as a condom or diaphragm) used with a spermicide, or (4) an intrauterine device (IUD). Contraceptive measures such as Plan B(TM), sold for emergency use after unprotected sex, are not acceptable methods for routine use. If you do become pregnant or have unprotected sex between the time you sign this consent form and your heart test, you must inform your study physician immediately.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct medical benefit to you. We hope that in the future the information learned from this study will benefit other people with symptoms possibly related to heart disease.

ARE THERE ALTERNATIVE TREATMENTS?

If you choose not to participate in this study, you will receive the standard testing and treatment if necessary. This will be determined by and discussed with your doctor. You will not be denied care based on your decision not to participate.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Information obtained from this research study will be submitted to the NHLBI, to its consultants who are helping conduct this study, and to the [INSERT IRB NAME] Institutional Review Board.

An Institutional Review Board (IRB) is a committee that has reviewed this research study to help guarantee that the rights, safety and welfare of the participants are protected and that the research is carried out in an ethical manner. Research study records may include the results of procedures and tests before or during the study, medical billing information, and other medical information relating to your study participation.

In addition, your study records may be reviewed by regulatory agencies in the US or other countries, such as the Office for Human Research Protections (OHRP) or the Food and Drug Administration (FDA). Reviewers may include, for example, representatives from the National Institutes of Health, the **[INSERT INSTITUTION/HEALTH CARE PROVIDER NAME]**'s Institutional Review Board (IRB), the Duke

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University Health System Institutional Review Board, the Data and Safety Monitoring Board, associates of the coordinating center for the study (the Duke Clinical Research Institute (DCRI)), **[INSERT SITE SPECIFICS]**, and **[INSERT OTHERS AS APPROPRIATE]**. If your research record is reviewed by any of these groups, they may also need to review your entire medical record. If photocopies are taken, your identity will be protected at all times because your name and personal details will be removed. For records disclosed outside of **[INSERT INSTITUTION/HEALTH CARE PROVIDER NAME]**, you will be assigned a unique code number. The key to the code will be kept **[INSERT INFORMATION WHERE CODE WILL BE KEPT]**.

Also, if a medical emergency occurs, your study information can be made available to your doctor and emergency personnel. Due to the need to release information to these parties, absolute privacy cannot be guaranteed; but, your confidentiality will be protected to the extent permitted by applicable laws and regulations. Only authorized staff will have access to your study records, except as the law may demand. The results of this research study may be presented at meetings or in publications, but you will not be identified by name.

The NHLBI requires that the data collected during a research study is made available to qualified investigators and non-study researchers. However, the institute also requires that your personal information, dates, or data that can identify you be removed or changed. The data will only be provided to investigators who agree in advance to adhere to established policies for distribution.

By signing this consent, you are authorizing the access described above.

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH CARE INFORMATION

The United States Government has issued a privacy rule to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The privacy rule is designed to protect the confidentiality of your health information in your medical record. This section, called an "Authorization," explains how your health information will be used and disclosed and describes your rights.

Protected Health Information (PHI)

By signing this informed consent document, you are allowing the investigators and other authorized personnel to use (internally at **[INSERT INSTITUTION NAME]**), and disclose (to people and organizations outside **[INSERT INSTITUTION NAME]**, identified in this consent) health information about you for the purposes of this research study. This may include information about you that already exists, such as your medical records, medical billing information, demographic information and laboratory tests, as well as any new information generated as part of this study. This is your Protected Health Information. This information may come from any health care providers or health care professionals or health plans that have provided health services, treatment, or payment for you such as physicians, clinics, hospitals, home health agencies, diagnostics centers, laboratories, treatment or surgical centers, health insurance plans, and government health agencies.

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People/Groups at [INSERT INSTITUTION NAME] That Will Use Your Protected Health Information

Your Protected Health Information may be shared with the investigators listed on this consent form as well as the supporting research team (such as research assistants, statisticians, data managers, laboratory personnel, administrative assistants). Your Protected Health Information may also be shared with the **[INSERT INSTITUTION IRB NAME]** and the Duke University Health System Institutional Review Board, as they are responsible for reviewing studies for the protection of the research subjects.

People/Groups Outside of [INSERT INSTITUTION NAME] with Whom Your Protected Health Information Will Be Shared

We will take care to maintain confidentiality and privacy about you and your Protected Health Information. We may share your Protected Health Information with the following groups so that they may carry out their duties related to this study:

- The sponsor of this study, the National Heart, Lung and Blood Institute
- The research organization that is managing this study, the Duke Clinical Research Institute
- The Duke Clinical Research Institute Outcomes and Follow-up Group
- The Duke University Health System Institutional Review Board
- Your health insurance company
- The US Department of Health and Human Services (DHHS), the US National Institutes of Health (NIH), and the US Office for Human Research Protections (OHRP)
- The Exercise ECG Core Lab, the Stress Echocardiogram Core Lab, the Stress Nuclear Core Lab or the Computed Tomography Angiography Core Lab
- American College of Radiology Imaging Network (where your heart test results/pictures will be sent and stored)
- Esoterix (the laboratory company where your blood samples will be sent if you have agreed to participate in the Biomarkers and/or Genomics part of the study)
- Almac Group (the company who will assign which heart test you receive)

Once your Protected Health Information has been shared with one or more of the groups listed above, there is a possibility that your information may be shared with other individuals or groups not involved in this study. If your information is shared, your Protected Health Information may no longer be covered by the federal privacy regulations, but everything possible will be done to ensure this does not occur.

Why We Are Using and Sharing Your Protected Health Information

The reason for using and sharing your Protected Health Information is to conduct and oversee the research as described in this Informed Consent Document. We will also use and share your Protected Health Information to ensure that the research meets legal and institutional requirements.

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No Expiration Date - Right to Withdraw Authorization

Your authorization for the use and disclosure of your Protected Health Information in this study will not expire until all study activities and data analyses have been completed. However, you may withdraw your authorization for the use and disclosure of your Protected Health Information at any time, provided you notify the study doctor in writing. If you would like to take back your authorization so that your Protected Health Information can no longer be used in this study, please send a letter notifying the study doctor of your withdrawal of your authorization to **[INSERT PRINCIPAL INVESTIGATOR NAME], [INSERT INSTITUTION NAME], [INSERT INSTITUTION ADDRESS]**. Please be aware that the investigators in this study will not be required to destroy or retrieve any of your Protected Health Information that has already been used or disclosed before the study doctor receives your letter.

If you want to participate in this research study, you must sign this consent and Authorization form to allow access to the health information about you. If you do not want to sign this form, you cannot participate in this research study. However, your decision not to provide your authorization will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care outside of this research study. .

Right to Access and Copy Your Protected Health Information

If you wish to review or copy your Protected Health Information as it is made part of your medical record, you may do so after the completion or termination of the study by sending a letter to the study doctor requesting a copy of your Protected Health Information. You may not have access to your study-related Protected Health Information until this study is completed or terminated.

You will be given a copy of this signed and dated form.

EXPIRATION DATE OR EVENT FOR RECORD RETENTION

This form will be retained for a minimum of six years after the study is completed.

Your study results will be retained in your research record for a minimum of six years after the study is completed. At that time, either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results at **[INSERT INSTITUTION/HEALTH CARE PROVIDER NAME]**. Any research information in your medical record will be kept indefinitely.

WHAT ARE THE COSTS?

If you are chosen to receive CTA, the cost of this test may be covered by you and/or your insurance company, and at least a portion will be paid by the grant for this study from the NHLBI. Any remaining cost not covered by the grant will be charged to you or your insurance company. Your insurance company or you will be charged or held responsible for the costs of your routine care (the care you would have received if you were not in this study). This includes the exercise ECG, stress echo or stress nuclear tests; pregnancy test if you are a woman capable of having children; and lab work for

creatinine values if not recently drawn for your regular medical care. Costs for other necessary therapies and tests not conducted under this study will be charged to you or your insurance.

WHAT ABOUT COMPENSATION?
You will not be paid for your participation in this study. (**Please note:** ***Compensation must be prorated so that if a subject withdraws from the study, the subject will receive compensation for the parts of the study he/she completed.***

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at **(insert your site info here**) in the event that you are injured as a result of your participation in this research study. However, there is no commitment by **(insert your site info here), Duke University Health System,** or your **(site)** physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact ***(insert PI's name here)*** at ***(insert PI's number here with area code)*** during regular business hours and at ***(insert PI's 24-hour number here with area code)*** after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor, the Duke Clinical Research Institute (DCRI) and the Data Safety and Monitoring Board (DSMB).

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you chose not to participate in this study, you will still receive treatment which is the standard of care including exercise treadmill testing, stress echocardiogram, cardiac nuclear imaging, or cardiac CT angiography. If you do decide to withdraw, we ask that you contact Dr. **[insert your PI's name here]** in writing and let **[him/her]** know that you are withdrawing from the study**. [His/her]** mailing address is **[insert PI's address here].**
You may also withdraw partially from the study as listed below:

- You may request that the study team no longer contact you during the follow-up period, but you may allow new information to be obtained from contacting your health care provider(s).

- You may request that the study team no longer contact you during the follow-up period, but you may allow new information to be obtained from your medical records.
- You may request that the study team no longer contact you during the follow-up period, but you may allow new information to be obtained from friends or family members you authorize to do so.
- You may request that the study team no longer contact you during the follow-up period, but you may allow new information to be obtained from public records.

You must specify in writing to the study investigator what follow-up you will allow, if any, at the time of withdrawal.

Dr. **[INSERT PI NAME]** may also ask you to provide some information about your health that would ordinarily occur when a person completes the study.

INVOLUNTARY WITHDRAW

Your doctor may stop your participation in this study without your consent if circumstances warrant doing so. The NIH, the National Heart, Lung and Blood Institute (NHLBI) or the DSMB may also stop the study for any reason.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have complaints, concerns or suggestions about the research, contact Dr. ***(PI's Name)*** at ***(PI's Number with Area Code)*** during regular business hours and at ***(PI's 24-hour Number with Area Code)*** after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the **(insert your IRB name here)** Institutional Review Board (IRB) Office at **(insert your IRB's phone number with area code).**

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed copy of this consent form."

_____ _____

Signature of Subject Date

_____ _____

Signature of Person Obtaining Consent Date