The Ohio State University
Consent to Participate in Research

Study Title: ***Magnetic Resonance Elastography of Cardiac Transplant Rejection***

Principal Investigator: ***Richard D. White, MD***

Sponsor: *Not Applicable*

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

- **Your participation is voluntary.** You may refuse to participate in this study. Even if you decide to take part in this research, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

- **You may or may not benefit as a result of participating in this study.** As explained below, your participation may result in: 1. Discovery of expected findings of importance to your care and shared with your primary physician; or 2. Unintended or harmful effects to you that may be minor or may be serious, but every possible precaution will be used.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy. You are being asked to consider participating in this study for the reasons explained below.

1. **Why is this study being done?**
   The aim of this study is to evaluate how well Magnetic Resonance Elastography (MRE) non-invasively predicts cardiac transplant rejection. MRE is a new FDA-approved (for liver fibrosis) method to take pictures of organs (like the heart, liver, spleen, and aorta) showing their stiffness. MRE combines magnetic resonance imaging (MRI) techniques with sound waves to take unique non-xray images (pictures) of organs, in this case, the heart. MRE allows us to determine the stiffening of the muscle of the transplanted heart, which we believe increases when the risk of cardiac transplant rejection increases.

2. **How many people will take part in this study?**
   Approximately 15 patients who have undergone heart transplantation at the Ohio State University - Ross Heart Hospital will participate in this study.

3. **What will happen if I take part in this study?**
   If you choose to take part in this study, you will continue to receive all of the medical care you would normally receive after your heart transplant surgery. Part of this care involves

regular heart muscle biopsies to see how your body is accepting your new heart. Beginning approximately 5-6 weeks after your transplant surgery, you will also have an MRE within a day or two of each biopsy.

The MRE is part of a heart MRI examination and will be performed on the MRI scanner in the Ross Heart Hospital if you are an in-patient, or on the MRI scanner at the Martha Morehouse facility (Kenny Road) if you are an out-patient. This type of scan does not require the use of any oral or intravenous contrast dye and does not expose you to any radiation.

You will first be asked to lie down on the bed of the MRI scanner. We will put small plastic ECG leads on your chest to measure your heart beat during scanning; for some people, we may have to shave parts of the chest to make sure the leads will stay in place. We will then place a small, circular, drum-like device (the driver) on your chest and secure it with Velcro straps. A hollow plastic tube that transmits sound waves, making the driver vibrate/hum during the scanning, is attached to the driver and a MRI coil (a type of antenna) is placed over the chest so we can receive the signal from the scanner. You will also receive earplugs because the MRI machine makes loud knocking noises during scanning.

For the scan itself you will be asked to lie flat inside the scanner. While inside the scanner, you will be able to speak to the technologist. We will also give you a “squeeze ball” to alert the technologist if you need urgent help.

While the machine is scanning, you will hear loud knocking noises and be asked to lie very still and occasionally to hold your breath. Most breath-holds should be approximately 10 to 15 seconds long. For some of the scans, we will vibrate the driver on your chest. Before we start any vibrations we will let you know. When the examination is finished, you will be free to leave the MRI area.

4. How long will I be in the study?

You will be enrolled in the study up to 6 months after your heart transplant procedure, during which you will be routinely asked to have the heart muscle biopsies; the MRE examinations will be added for research comparison. No extra biopsies will be performed due to your involvement in this research.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

MRE, which is a form of MRI, is a low-risk procedure and very safe. MRI uses powerful magnets to make images. This has the benefit of not involving radiation. However, it also

means that people who have certain types of metal or electronic devices in their body cannot undergo an examination.

The risks of MRI/MRE without contrast to an unborn child are not known. If you are a woman of child bearing potential, a routine urine pregnancy test will be done immediately prior to your MRE scan. If the pregnancy test determines you may be pregnant, the MRE scan will not be performed.

Possible Metallic Attraction or Electronic Device Disruption:
You will be screened for such objects. If overlooked during the screening process, some metal objects may move or heat up during the scanning. Electronic devices (such as pacemakers, defibrillators, or nerve stimulators) may either shutoff or become dysfunctional. If any metal or electronic devices are discovered during the scanning, the examination will be stopped and you will be taken out of the MRI room. A Radiology physician will then evaluate you and decide if any evaluation or treatment is needed. Further participation in the study will be discontinued.

Possible Claustrophobia:
Some people with claustrophobia may feel too closed in and may not tolerate MRI scanning. If you feel too confined in the MRI scanner you can inform the technologist and the MRI scan will be stopped.

Possible Discomfort/Hearing Damage from Noise:
The MRI machine makes loud knocking sounds when it is scanning. Because of this, you will be asked to wear earplugs while getting your MRI examinations. The earplugs minimize discomfort from noise and keep the MRI noise within the safety range.

7. What benefits can I expect from being in the study?
You may or may not benefit if you participate in this study. The potential benefit to heart transplant patients in the future is the ability to detect cardiac transplant rejection using non-invasive (no biopsy) MRE technology.

However, if any unexpected key findings important to your health are noted by the investigators during the routine MRI portion of your research examination, they will be shared with your primary physician.

8. What other choices do I have if I do not take part in the study?
You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled. Not participating will in no way affect any medical care you would normally receive following your heart transplant.

9. Will my study-related information be kept confidential?
Every effort will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- Your insurance company (if charges are incorrectly billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information.

10. What are the costs of taking part in this study?

There is no additional cost for participating is this trial. Neither you nor your insurance company will be charged for the research specific MRE exams.

11. Will I be paid for taking part in this study?

You will not be paid for participating in this research study. Transportation and parking charges specifically related to MRE will be reimbursed. At each MRE appointment, you will receive $20.00 in pre-paid gas cards, up to $100.00 per year, to help offset the cost of participating in this study. By law, payments to subjects are considered taxable income.

12. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the study doctor or another researcher immediately, in order for them to determine if you should obtain medical treatment at The Ohio State University Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.
You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?
For questions, concerns, or complaints about the study you may contact **Richard D. White, MD at 614-293-4456** or **Barbara McCracken, CCRC at 614-688-8934.**

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **Richard D. White, MD at 614-293-4456.**

Signing the consent form.

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in this research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
	AM/PM
Relationship to the subject	**Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	Signature of person obtaining consent
	Date and time **AM/PM**

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	Signature of witness
	Date and time **AM/PM**

Printed name of witness	Signature of witness
	Date and time **AM/PM**