

FOR CCI USE ONLY		
approved by the Beth Israel Deaconess Medical Center Committee on Clinical Investigations, New Procedures and New Forms of Therapy:		
Administrator: _____	Date: _____	

Protocol	Number: _____	Expiration
Date: _____		

INFORMED CONSENT

- Subject's name: _____
- Title of Research Protocol: **Magnetic Resonance Imaging in Coronary artery disease**
- Principal Investigator's Name: **Roger Laham**
- Co-Investigators: **Robert Edelman, PV Prasad, Michael Simons, Paula Rooney, Deana Neiman, Deborah Hoyle, Theresa Bishop, Cathy Ross, Donald Baim, David Cohen, Joseph Carrozza, Richard Kuntz, Justin Pearlman**
- Protocol Number: 99-164

In order to decide whether you wish to participate in this research study, you should understand enough about its risks and benefits to be able to make an informed decision. This process is known as “informed consent”.

This consent form provides detailed information about the research study, which your doctor will discuss with you. After your questions have been answered about the study and if you decide to participate, you will be asked to sign this informed consent form. You will receive a copy of the signed form to keep for your records.

D1. PURPOSE OF STUDY:

The purpose of this study is to determine the value of magnetic resonance imaging (MRI) to detect and measure changes in heart function and myocardial (heart) blood flow with coronary artery disease or “hardening of the arteries” before and after the administration of recombinant basic fibroblast growth factor (rFGF-2), laser myocardial revascularization, or angioplasty. This imaging technique uses magnetic fields and radio waves to obtain information about the function of the heart and blood flow in the heart of patients with cardiovascular disease, and patient who have been treated with a rFGF-2, laser myocardial revascularization, or angioplasty to induce the formation of new blood vessels in the heart.

D2. SUBJECT SELECTION:

Your doctor has determined that you have coronary artery disease. The arteries of your heart have developed atherosclerotic (“cholesterol”) blockages which may cause you to experience chest pain, angina, or even heart attacks due to decreased blood flow to your heart. After reviewing the results of your cardiac catheterization, your doctor has determined that you may not be a candidate for coronary artery bypass surgery or balloon angioplasty and has recommended that you participate in the rFGF-2 study or laser myocardial revascularization study for which you have signed a separate informed consent. You are asked to participate in an MRI study that will attempt to determine

whether you benefited from the treatment with rFGF-2 or laser myocardial revascularization. In addition, if you end up having a angioplasty or bypass surgery because of

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progression of disease since your last catheterization, MRI will be performed 3 months and 6 months after angioplasty or bypass surgery. If you choose not to participate, your care will occur as scheduled, but you will not have the MRI examination.

D3. PROCEDURE:

You will be asked to lie down on a table unit, which will then slide you into a large donut-shaped MRI machine. This research machine is especially equipped for fast imaging. Your heart rate will be monitored for timing purposes and for safety. A heating pad, which is normally used in hospitals for physical therapy purposes, may be applied to the region of imaging for the purpose of adjusting the local temperature not more than 3 degrees. A smaller device called a receiver coil will be placed over the region to be imaged to improve signal quality. You will be required to lie still for up to 10 minutes at a time. For certain scans you may be asked to hold your breath for 10-20 seconds, and you will receive contrast (a substance that enhances MRI images) administered through an intravenous (through a vein) line. Certain scans may use the special capability for fast imaging. The examination will last approximately 1 hour. A set of images will be obtained after the administration of an agent that simulates stress (dipyridamole), which you may have already received with your nuclear stress test. You will be monitored closely during this infusion. The additional images take approximately 10-15 minutes to obtain.

The above procedures will be performed during the screening period before your cardiac catheterization to receive study drug, laser myocardial revascularization or placebo (no active treatment), and at 90 and 180 days following the treatment. If you end up having an angioplasty or bypass surgery because of progression of disease since your last catheterization, MRI will be performed 3 and 6 months after angioplasty or bypass surgery.

D4. RISKS AND DISCOMFORTS:

We will ask you a series of questions prior to your study to make sure that there are no reasons for you not to participate in an MRI exam (such as pacemaker, electronic implants, shrapnel in the eye, certain intracranial aneurysm clips). Assuming that none of these reasons exist, there is no known risk from MRI, which is a well utilized, accepted, and FDA approved procedure that is commonly used to image different parts of the body. There are no known immediate or delayed risks from MRI imaging. No delayed complications from MR examination have been encountered, and it is expected that the potential risk for any delayed complication is extremely small or non-existent. Some individuals experience claustrophobia when undergoing the MR examination. The staff will provide every possible means to reduce this sensation.

There is no x-ray or other ionizing radiation exposure from MRI. If you have a large metallic implant or certain kinds of tattoos, you could feel some discomfort or tingling from local heating effects.

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You will receive an MRI contrast agent. This will require placement of an intravenous (through a vein) line which may cause some mild discomfort or bruising at the intravenous site; occasional feeling of lightheadedness; and rarely, infection at the site of the infusion. There are no known reasons you should be at any particular risk from MRI contrast agents. Fewer than 10% of subjects receiving such agent identified any complaints. Of those who had complaints, 8.7% reported mild to moderate headache, 4.8% reported coldness at the infusion site and 3.2% reported nausea.

You will receive a stress agent (dipyridamole) which you may have already received during the nuclear stress test (nuclear thallium/sestamibi test) This agent may cause you to have angina (stressing of your heart), however, you will be monitored for side effects and the medicine can be reversed if they arise. In rare circumstances, the medicine may cause irregularities in the heartbeat, including ventricular fibrillation and cardiac arrest, which will be treated by the monitoring cardiologist. A Physician experienced in administering this stress agent will be available at all time during the administration of the medicine (over 4 minutes), then full reversal of the medicine will be performed immediately after image acquisition.

When very high-speed methods are used for imaging, you may experience a mild twitching sensation. This should not be uncomfortable, but you should let the staff know if you experience this sensation so the staff can modify the imaging method to eliminate it.

D5. BENEFITS:

You are being asked to participate in this study voluntarily. MRI may detect abnormalities or changes not seen by other tests. However, there may be no direct benefit to you by participating. It is hoped that this study will provide valuable information that will lead to further improvements in the treatment of patients with coronary artery disease.

D6. ALTERNATIVE PROCEDURES:

Your decision to participate in this study is voluntary and will not affect your present or future medical care at the Beth Israel Deaconess Medical Center. You will have your other scheduled tests for the FGF-2 study, laser myocardial revascularization, or angioplasty studies, regardless of whether you choose to participate in the MRI study. Whatever your decision is, your care is independent of your participation in this study.

D7. COST/PAYMENT:

You will not be charged for procedures that are related to the conduct of the study and are not part of your routine care. You or your insurance provider will be responsible for costs that are unrelated to research. If you have questions about the costs, you should ask your doctor.

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D8. COMPENSATION FOR INJURY:

If, during the course of the study, any injury should occur to you, you must contact a member of the research team immediately. Beth Israel Deaconess Medical Center will provide medical treatment for any illness or physical injury directly resulting from research procedures.

D9. PARTICIPATION AND WITHDRAWAL:

You may refuse to participate or withdraw from the study at anytime without penalty or loss of benefits and without affecting your future medical care. Should you refuse to participate in this research study, you will receive the normal care for patients with coronary artery disease. Your doctor may stop your participation in this study at any time if it is in your best interest medically.

If new information, which could affect your willingness to participate in this study comes to the attention of the investigator, you will be notified. If new treatments develop which indicate that this treatment is not in your best interest, the treatment will be stopped.

D10. CONFIDENTIALITY:

Information derived from this study and from your medical record may be reviewed and photocopied by the Food and Drug Administration (FDS) and/or state and federal regulatory agencies, the study sponsor and the Committee on Clinical Investigations of the Beth Israel Deaconess Medical Center with protection of confidentiality so far as permitted by applicable law. Information resulting from this study and from your medical record may be used for research purposes and may be published, however, you will not be identified by name in such publications.

If you have any questions or experience problems you should contact Dr. Roger Laham at (617) 667-4138.

Date submitted to Committee: _____

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CONSENT FORM FOR CLINICAL RESEARCH

I have read the previous page(s) of the consent form and the investigator has explained the details of the study. I understand that I am free to ask additional questions.

If I wish additional information regarding this research and my rights as a research subject, or if I believe I have been harmed by this study, I may contact the Chairman of the Medical Center's Committee on Clinical Investigations at (617) 667-4272

I am aware that this is a research project and that unforeseen side effects may occur.

I understand that the Beth Israel Deaconess Medical Center has no formal program for compensating patients for medical injuries arising from this research. Medical treatment will be provided for injuries at the usual charge to me or to my insurer unless payment is otherwise provided for in this consent form.

I understand that I may be contacted by the Beth Israel Deaconess Medical Center's Committee on Clinical Investigations during or after my participation in this study as part of its efforts to monitor the experience of subjects in clinical investigations.

I understand that participation in this study is voluntary and I may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.

I acknowledge that no guarantees have been made to me regarding the results of the treatment involved in this study, and I consent to participate in the study and have been given a copy of this form.

_____	_____	_____	_____
WITNESS	DATE	STUDY SUBJECT	DATE
		_____	_____
		PARENT OR LEGAL GUARDIAN	DATE
		(If subject is a minor, or subject is unable to give consent)	

The subject has been given the opportunity to read this consent form and to ask questions before signing, and has been given a copy.

_____	_____	_____
PRINT INVESTIGATOR'S NAME	SIGNATURE OF INVESTIGATOR (or designee)	DATE
For any questions regarding the rights of a research subject, or information regarding treatment of research-related injuries, please contact Nan Clark, Manager, Research Administration, (617) 667-3743		

