RESEARCH CONSENT FORM

Basic Information

Title of Project: Endothelial Health across the Spectrum of Cardiometabolic Disease

IRB Number: H-43569

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Framingham Heart Study Center Phone Number: (508) 872-6562 or (800) 854-7582
24 hour phone number: 617-358-1212

Overview

We are asking you to be in a research study. A research study is an organized way of collecting information about scientific questions. This form will tell you what you should expect if you agree to be in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form.

It is your decision whether or not to join the study. We are asking you to be in this study because you are a participant in the Framingham Heart Study. We are doing the research to study changes in the function of endothelial cells (which form the inner lining of blood vessels), as these changes are believed to relate to heart function. If you agree, you will participate in endothelial cell collection. Your participation in the cell collection should take 20 - 30 minutes. You will find more information about what will happen in this study later in this form.

The main risks of being in the study are momentary discomfort and slight risk of bruising or infection at the puncture site during cell sample collection. You will find more information about risks later in this form.

Purpose

The purpose of this study is to determine how endothelial cell health relates to risk factors for heart disease including diabetes and obesity. The study will help us understand the causes of atherosclerosis, a condition where arteries are thickened or hardened by a buildup of plaque, which may lead to heart attack and stroke.

What Will Happen in This Research Study

You will be one of approximately 2,000 subjects who will be asked to be in the study.

The research will take place at the following location(s): Framingham Heart Study

This study consists of one visit to Framingham Heart Study and will last about 20 - 30 minutes.

We will ask you not to eat or drink (except water) for at least 4 hours prior to your study visit on the day of the study.
During the study visit we will:

- Confirm that you meet the study inclusion criteria by short interview. Pregnant women are excluded from this study. If you are a woman with childbearing potential, we will perform a urine pregnancy test to be sure that you are not pregnant.
- Place an intravenous (IV) line in a vein of your arm. An IV is a thin, plastic tube.
- Collect endothelial cells from a vein (cells from the inner lining of a blood vessel). We will insert a soft J-shaped wire through the IV in your arm, and then remove the wire. We will repeat the wire insertion up to three additional times. The wire measures 0.018 inches in diameter. On average we will insert the catheter about 2inches (5cm) into the vein. We have learned that during this process a small number of endothelial cells stick to the wires and can be washed off for study under the microscope. We will study the biological characteristics of these cells to better understand the potential effects of diabetes, obesity and other risk factors for heart disease. These wires are routinely used to insert catheters into patients' veins. The cell collection will be performed by a nurse or physician, and no more than three attempts will be made to collect the cells.

We will measure proteins and ribonucleic acid (RNA) from your cells. RNA is a molecule that is in all of your cells and carries information to tell the genes what proteins to make. Measuring the RNA levels will help us better understand links between risk factors for heart disease and blood vessel health. We are not studying DNA, which is the molecule in your genes, in the endothelial cells.

These samples will be labeled with a code number and not your name.

After we measure the RNA and protein, any additional cell samples will be frozen indefinitely in a locked freezer for future study of endothelial dysfunction. No cell lines will be established. Coded samples may be released to investigators at other academic institutions to the purpose of measuring new markers of cardiovascular risk. All subject identifiers will remain at FHS. FHS Investigators will maintain the master-code/key and will never release it to outsiders. You can withdraw your permission for long-term storage at any time by calling Dr. NAOMI HAMBURG at 617-515-2650. You do not have to agree to long-term storage to participate in the study.

Please circle yes, if you agree to storage and no, if you do not agree:

Yes | No Subject initials: _____

Information such as demographic, medical and other clinical information, and questionnaire responses collected as part of your participation in other FHS studies may be used for this project as well.

Risks and Discomforts

Taking the cell samples will cause momentary discomfort and on rare occasions fainting. There is a slight chance that a bruise or infection will develop at the puncture site.

There is a very slight possibility for the J-shaped wire inserted into the vein for endothelial cell collection to malfunction. Because only a very small part of the wire is placed in the vein beyond the plastic catheter and the wire is very gently moved to get the cells, it is extremely rare for a part of the wire to break off and go into the body. In the very rare case that this happens, you might need a procedure to remove the part of the wire that broke off from your body. It could also puncture a blood vessel. We have performed this procedure in over 2500 individuals and never observed any complications regarding the wires. All the J-wires are inspected prior to the procedure and the procedure is performed by a trained and experienced nurse or physician.

There may be unknown risks or discomforts involved.

There is a risk to the confidentiality of your health information. We take special efforts to protect your health information, but there is a small chance of a data breach. The ways we will protect your privacy and confidentiality are described in a separate section later in this form.

Potential Benefits

You will receive no direct benefit from being in this study. The primary goal of this research is to collect information about the scientific questions asked in this study. Your being in this study may help the investigators learn how diabetes and obesity lead to higher risk for heart disease.

Costs

There are no costs to you for being in this research study.

Payment

You will not be paid for being in this study.

Confidentiality

We must use information that shows your identity to do this research. Information already collected about you will remain in the study record even if you later withdraw.

We will store your information in ways we think are secure. We will store biological samples taken from your body in a locked freezer in a locked research unit. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. Only the people listed later in this section will be given access to your information. However, we cannot guarantee complete confidentiality.

This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information or biological samples are covered by a CoC**.** The CoC provides how we can share research information or biological samples. Because we have a CoC, we cannot give out research information or biological samples that may identify you to anyone that is not involved in the research except as we describe below. Even if someone tries to get your information or biological samples in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information. Samples that are collected from you in this study will be analyzed to find out information about your genetics. Your genetics and health information, without your name or other data that could easily identify you, will be put in a database run by the National Institutes of Health (NIH).

If you agree to be in the study and sign this form, we will share information and biological samples that may show your identity with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.
- People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
- People who will get information and biological samples from us, such as investigators at other academic institutions, for other research studies involving measuring new markers of cardiovascular risk. These people are expected to protect your information and biological samples in the same way we protect it.
- Any people who you give us separate permission to share your information.

We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

- Publishing results in a medical book or journal.
- Adding results to a Federal government database.
- Using research data in future studies, done by us or by other scientists.
- Using biological samples in future studies, done by us or by other scientists.

Compensation for Injury

If you think that you have been injured by being in this study, please let the Principal Investigator know right away. Use the phone number on the first page of this form. If you have a health emergency, get care first. You can seek treatment for the injury at Boston Medical Center or at any healthcare facility you choose. Tell the doctors that you are in this study.

There is no program to provide compensation for the cost of care for research related injury or for other expenses. Other expenses might be lost wages, disability, pain, or discomfort. You or your insurance will be billed for the medical care you receive for a research injury. You are not giving up any of your legal rights by signing this form.

Subject's Rights

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study. You will be given a copy of this form to keep.

If you do not agree to be in this study or if at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you. Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact Dr. Naomi Hamburg at 617-358-1202. Also call if you need to report an injury while being in this research.

You may also call 617-358-5372 or email medirb@bu.edu. You will be talking to someone at the Boston Medical Center and Boston University Medical Campus IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

BMC and BU Medical Campus IRB
IRB NUMBER: H-43569
IRB APPROVAL DATE: 10/23/2023

Subject: _____
Printed name of subject

By signing this consent form, you are indicating that

- you have read this form (or it has been read to you)
- your questions have been answered to your satisfaction
- you voluntarily agree to participate in this research study
- you permit the use and sharing of information that may identify you as described

_____ _____
Signature of subject Date

Researcher: _____
Printed name of person conducting consent discussion

I have personally explained the research to the above-named subject and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

_____ _____
Signature of person conducting consent discussion Date

To be completed by witness if researcher reads this form to the subject
This consent form was read to and apparently understood by the subject in my presence.

_____
Printed name of witness (a person not otherwise associated with the study)

_____ _____
Signature of witness Date