RESEARCH CONSENT FORM
CTADD Exam 2 - Offsite

H-22762- THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

Background

The Computed Tomography (CT) Study is an observational research study designed to identify the relationship between calcium deposits in your arteries, fat deposits, and lung function with other health conditions. You are being asked to participate in this study because you are a woman over the age of 40 or a male over the age of 35 and are enrolled in the research study entitled the Framingham Heart Study. The study is sponsored by the National Institutes of Health (NIH) and is conducted in collaboration with the Massachusetts General Hospital (MGH).

The CT scan that you will undergo is very similar to the one that you had previously. However, there are a few differences. The CT machine is newer and stronger. Instead of two scans of the chest, we will only perform one. You will also undergo a CT scan of your abdomen similar to the one that you had previously.

Purpose

The purpose of this research study is to investigate the role of calcium deposits in your arteries, fat deposits, and lung function in the development of 1) heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, joint disease, bone loss, cancer, and other major diseases and health conditions; and 2) metabolic conditions including diabetes and high cholesterol; and 3) to examine the role of inherited factors (genes) in calcification of the arteries, fat deposits, and lung function.

What Happens In This Research Study

You will be one of approximately 2900 subjects to be asked to participate in this study.

The research will take place at the following location(s): Boston University Medical Center.
Your CT examination will take place at the PARC Center, located at 40 Second Avenue, Suite 120 (CT/MRI Services) in Waltham, MA at Massachusetts General Hospital West or at 80 Everett Avenue, Chelsea, MA 02150 at Mass General Imaging Chelsea. The examination will take approximately 30 minutes and will include the following Computed Tomography scan taking about 15 minutes:

1) The CT Scan
A Computed Tomography (CT) scan will be performed for research purposes. This is an x-ray done to measure the amount of calcium in the arteries of your heart and abdomen, fat in the abdomen, liver, and around the heart, and lung function.

One scan of your chest and one scan of your abdomen will be performed. For this scan, you will lie on a table with just your torso (not your head) inside the doughnut shaped CT scanner. You will be asked to remain still and hold your breath for about 20-30 seconds during the scan.

2) Pregnancy Test (for some women only)
Most women will be asked to provide a urine sample for a pregnancy test within 24 hours before the CT scan. Women who are not pregnant after undergoing the pregnancy test will proceed with the CT scan. If the pregnancy test is positive, you will be referred to your physician for follow up and the scan will not be performed.

This CT scan will not be done on women who are pregnant or who have been breast feeding for less

than six months.

3) Results
When the CT scan is read the amount of calcium in your arteries is given a score. At present, it is the opinion of experts that the scores of the amount of coronary calcium detected by CT scanner are not usually used to make clinical decisions. Therefore, the results of the calcium tests or of genetic research that results from the CT scanning tests will not routinely be reported to your physician. However, markedly abnormal levels of calcium deposits in your arteries will be reported to your physician. If you don't have a doctor, you can be referred if you so desire.

In addition, your images will be reviewed for the presence of other findings. In the event that this reading will detect potential medical problems that require further diagnostic testing or treatment, you will be notified and a letter will be sent to you and your physician or the clinic that you choose with your permission.

Because a complete clinical evaluation of the CT scan images for all possible abnormalities in the chest and abdomen will not be performed, some clinically important findings may not be discovered.

You will be asked to sign an additional medical release form giving permission to MGHW or MGH Chelsea to release your CT information to the Framingham Heart Study Investigators.

The results of your CT scans will be shared with the Framingham Heart Study investigators. To ensure confidentiality, a code number will be assigned to all subjects and any other potentially identifying information will not be used on any information provided by subjects. When study results based on subject information are published, names and other potentially identifying information will not be revealed. Only the code numbers will be provided to qualified investigators studying the information.

Any questions you have regarding your rights as a research subject may be directed to the Office of the Institutional Review Board of Boston Medical Center at (617) 638-7207. The Framingham Heart Study is a medical research project sponsored by the National Institutes of Health. It is authorized under 42USC 285b-3. The system of records which applies to the Framingham Heart Study is documented in the Federal Register: September 26, 2002 (Vol. 67, No. 1879) pages 60776-60780.

Risks and Discomforts

The CT scan of the chest and abdomen involves low doses of radiation. The total amount of radiation per scan is approximately 5 mSv (millisievert). A millisievert is a unit of measure of radiation dose. This amount of radiation represents less than 10% of the yearly radiation exposure limit allowed for a radiation worker. Another way of understanding this is that the total amount of radiation is less than the radiation exposure from 2 mammograms.

The risk from this amount of radiation (X-rays) is generally recognized to be safe by the Food and Drug Administration (FDA) for such studies.

We do not expect an unusual risk or injury to occur as a result of your participation. However, there may

be unknown risks/discomforts involved. Study staff will update you in a timely way on any new information that may affect your health, welfare, or decision to stay in this study. In the unlikely event that during examination procedures you should require medical care, first aid will be available.

There may be unknown risks/discomforts involved. Study staff will update you in a timely way on any new information that may affect your health, welfare, or decision to stay in this study

Potential Benefits

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand the causes of heart disease, and prevention of cardiovascular disease and other medical conditions involving the heart, including the possibility of genetic linkages. These studies may also lead to the development of new methods of prevention and treatment of these diseases.

Alternatives

Your alternative is to not participate in the study.

Subject Costs and Payments

You will not be charged for the scan. If the research evaluation of the CT scan examination uncovers markedly abnormal levels of calcium deposits in your arteries or any medical problems that require medical diagnosis or treatment, you will be so advised and that information will be provided to the physician or clinic that you choose.

In the event that your physician decides that follow up clinical tests or treatments are necessary, payment must be provided by you or your third party payer, if applicable (for example, health insurance or Medicare). No special arrangements will be made by the Framingham Heart Study for compensation or for payment of treatment solely because of your participation in this study. This does not waive any of your legal rights.

Costs that you might incur the day of your participation include, but are not limited to, loss of work, and transportation (gas, tolls, etc.). You will not receive payment for your participation. However, if necessary, we will provide transportation from the Framingham Heart Study to and from the center at no cost.

Confidentiality

Any information we obtain about you during this study will be treated as strictly confidential to the full extent permitted by applicable law. To ensure confidentiality, a code number will be assigned to you and any of your potentially identifying information. The code numbers will be provided only to qualified investigators.

You will not be informed of the results of the research including the genetic research that may arise from the CT scan, although genetic tests may be developed as a result of the combined analysis of data in the Framingham Heart Study.

When study results based on your information are published, your name and any other potentially

identifying information (i.e. code numbers) will not be revealed. You will be kept informed through periodic publications from the Framingham Heart Study of any new information of findings about CT testing or genetic findings related to CT testing, which may be of importance to you and/or your family.

To help us further protect your privacy, the investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes. You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note however, that if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy. Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

Please check the appropriate box that you agree with:

|___| YES |___| NO I agree to allow the Framingham Heart Study to release the findings from CT scan to my physician, clinic, or hospital.

Subject's Rights

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

If at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled.

You may obtain further information about your rights as a research subject by calling the Office of the Institutional Review Board of Boston University Medical Center at 617-638-7207.

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, or if you need to report an injury while participating in this research, contact DR. CAROLINE FOX at (508) 872-6562.

Compensation for Research Related Injury

If you think that you have been injured by being in this study, please let the investigator know right away. If your part in this study takes place at Boston Medical Center, you can get treatment for the injury at Boston Medical Center. If your part in the study is not at Boston Medical Center, ask the investigator

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where treatment for injury would be available locally. You and your insurance company will be billed for this treatment. Some research sponsors may offer a program to cover some of the treatment costs which are not covered by your insurance. You should ask the research team if such a program is available.

Right to Refuse or Withdraw

Taking part in this study is voluntary. You have the right to refuse to take part in this study. If you decide to be in the study and then change your mind, you can withdraw from the research. Your participation is completely up to you. Your decision will not affect your being able to get health care at this institution or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

If you choose to take part, you have the right to stop at any time. If there are any new findings during the study that may effect whether you want to continue to take part, you will be told about them as soon as possible.

The investigator may decide to discontinue your participation without your permission because he/she may decide that staying in the study will be bad for you, or the sponsor may stop the study.

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

_____ _____
Subject (Signature and Printed Name) Date

_____ _____
Person Obtaining Consent (Signature and Printed Name) Date