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RESEARCH CONSENT FORM
CTADD Exam 1 - 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 the coronary arteries and 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 Framingham Heart Study.

Purpose
The purpose of this research study is to investigate the role of calcium deposits in the aorta and coronary arteries in the development of 1) heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, joint disease, bone loss, deafness, cancer, and other major diseases and health conditions; and 2) to examine the role of inherited factors (genes) in calcification of the aorta and coronary arteries.

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 research 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. The examination will take approximately 30 minutes and will include the following Computed Tomography scan taking about 20 minutes:

1) The CT Scan
A Computed Tomography (CT) scan will be performed for research purposes at Mass General Hospital West (MGHW) Medical Center in Waltham, MA. This is a new type of x-ray done to measure the amount of calcium in the arteries of your heart and abdomen.

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 several times during the scan.

Two scans of your coronary arteries and one scan of your abdominal aorta will be performed.

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 results 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.

A complete clinical evaluation of the CT scan image for abnormalities in the chest and abdomen will not be performed for clinically important findings.

Incidental Findings: In the event that the research evaluation of the scan does uncover medical problems that require medical diagnosis for treatment, you will be told and the information will be provided to the physician or clinic that you choose.

This CT scan is being conducted for research purposes. The CT scan is being done only to measure calcium in the heart and major arteries. 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 to release your CT information to the Framingham Heart Study Investigators.

Any questions you have regarding your rights as a research subject may be directed to the Office of the Institutional Review Board for 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 heart and abdomen involves low doses of radiation. The total amount of radiation per scan is 1 msv or less than 8% of the yearly radiation exposure limit allowed for a radiation worker. Another way of understanding this is that the total amount of radiation is approximately equivalent to 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. 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 precursors, etiology, and prevention of cardiovascular disease and other medical conditions involving the heart, including th epossibility of genetic linkages .

Alternatives

Your alternative is to not participate in the study.

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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 FHS 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 for cardiovascular disease or other health conditions, which may be of importance to you and/or your family.

Information from this study and from your medical record may be reviewed and photocopied by the Food and Drug Administration (FDA) and/or state and federal regulatory agencies such as the Office of Human Research Protection as applicable, and the Institutional Review Board of Boston University Medical Center.

Please check the appropriate box that you agree with:

I___IYES I___INO
I agree to allow the Framingham Heart Study to release the findings from tests and examinations to my physician, clinic, or hospital.

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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. If this study is being done outside the United States you can ask the investigator for contact information for the local Ethics Board.

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 PHILIP WOLF 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 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.

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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