Framingham Heart Study
Offspring Exam 10, Omni 1 Exam 5
Bone Study Informed Consent Form ADDENDUM

Basic Information

Title of Project: Framingham Heart Study

IRB Number: H-32132

Sponsor: National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH)

Principal Investigator: Vasan S. Ramachandran, MD
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Study Phone Number: (508) 872-6562 or (800) 854-7582

PI Phone Number: (617) 358-1310 for Dr. Vasan S. Ramachandran

Overview of the Bone Study at the Framingham Heart Examination

We are interested in learning about how the skeleton changes with aging. We will ask you to participate in two bone scans to examine the bone structure in your lower leg and lower arm. The scan is a non-invasive and painless test, and provides a detailed image of the "micro-architecture" inside the bone. Each scan takes about two minutes and requires that you keep as still as possible.

The research examination that will be conducted as part of this study is not clinical care. The tests are for research purposes only. We do not provide medical services. This research examination does not take the place of medical care by your own health care provider.

About your consent

Please read this research consent form carefully. It tells you important information about the research study. Taking part in a research study is voluntary. The decision whether or not to take part in all or any part of the research exam is entirely up to you. If you choose to take part, you can decide to stop at any time. Your decision will be honored and respected. There will be no penalty to you if you decide to stop or not to take part.

If I have questions or concerns about this research study, whom can I call?

If you have any questions about the research or about this form, please ask us. You can call us with your questions or concerns. You can ask questions as often as you want.

You can call a study staff member directly at (508) 872-6562 or (800) 854-7582, or you can send an email to FHS@bu.edu.

The Framingham Heart Study is led by investigators from Boston University and the National, Heart, Lung, and Blood Institute at the National Institutes of Health. Dr. Vasan S Ramachandran and Dr. Daniel Levy are in charge of the research study. You can contact Dr. Ramachandran at (617) 358-1310 Monday through Friday between 9am and 5pm or by email at vasan@bu.edu and Dr. Daniel Levy at (508) 935-3400 Monday to Friday between 9am and 5pm or by email at levyd@nih.gov.

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.

Overall Examination Risks and Discomforts
Bone scans involve the use of x-rays, a form of energy also called radiation. The radiation dose for the two scans together will be less than 10 μSv, which is equivalent to 2-3 days of background radiation that individuals experience in the U.S. Since the amount of radiation from the bone scans is so small, there are no known long-term effects of this radiation on your health. However due to potential risk to a fetus, pregnant women, as determined by self-report or by a positive pregnancy test, will be excluded from this test.

We do not expect any risk of injury as a result of your participation in the study. However, first aid will be available.

Unknown Risks: There may also be some risks that we are unable to determine at this time.

How is my information protected?

We will store your information in ways we think are secure. We label your samples and information with a code, and we keep the key to the code in a password protected database. Only approved staff is given the password. We use other safeguards at our facilities and for our information technology and systems to protect the privacy and security of your information.

We do not sell, rent, or lease your contact information.

If information from this study is published or presented at scientific meetings, and when your samples and information are shared with other researchers and deposited in data and specimen banks and repositories, your name and other direct personal identifiers will not be used.

However, we cannot guarantee total privacy. We may provide access to your information in order to do the study and to make sure we do the study according to certain standards set by ethics, law, and quality groups. Information may be made available to researchers that are part of this study, the Institutional Review Board that oversees this research, research and non-research staff and organizations who need the information to do their jobs for the conduct and oversight of the study, people or groups that we hire to do work for us (such as data or biosample storage companies, insurers, and lawyers), and Federal and state agencies as required by law or if they are involved in the research or its oversight. In most cases, any information that is given out to others is identified by code and not with your name or other direct personal identifiers. Once information is given to outside parties, we cannot promise that it

will be kept private. Please be aware that your personal information may be given out if required by law (e.g., to prevent possible injury to yourself or others).

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.

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.
- Investigators who will get your data and your biological samples as we described in the section "*What will happen in this research study?"* 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.

You should know that we are required to report information about child abuse or neglect; elder abuse; specific reportable diseases; or harm to others.

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.

Samples that are collected from you in this study will be analyzed to find out information about your genetic makeup. 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). This may include your whole genome information. Other researchers can ask the NIH to get your information from the database. You should know that it is possible that your genetics information might be used to identify you or your family, though we believe it is not too likely that this will happen. Once your information is given to the NIH database, you can ask to have NIH stop sharing it, but NIH cannot take back information that was already shared.

Patenting Discoveries

Research from this study may, one day, result in new tests to diagnose or predict diseases. It may also lead to the development of new ways to prevent or treat diseases. As is true of all federally-funded research, researchers and their employers are permitted by Federal law to

patent discoveries from which they may gain financially. You and your heirs will not benefit financially.

What are the possible benefits from being in this research study?

While you will not receive any direct benefit as a result of your participation in this study; we hope that this study will help us better understand what causes heart disease and other diseases and conditions and how to better prevent and treat them.

What are the costs of taking part in the study?

Costs that you may incur on the day of your participation include, but are not limited to, loss of work and transportation costs (gas, tolls, etc.).

You will not be paid for your participation in this study.

No special arrangement will be made by the Framingham Heart Study for compensation or payment solely because of your participation in this study. If you think you have been injured by being in this study, please let the investigators know right away. Boston University and the sponsors do not offer a program to provide compensation for the cost of care for research related injury or other expenses such as lost wages, disability, pain, or discomfort. You will be sent a bill for the medical care you receive for research injury if your medical insurance does not pay for your medical care. This does not waive any of your legal rights.

How long will I be in the study?

FHS is a long-term study.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

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.

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, including your health information.

To be completed by subject if personally signing

_____ _____
Signature of subject Date

To be completed by LAR if subject does not personally sign
I am providing consent on behalf of the subject.

_____ _____
Printed name of Legally Authorized Representative (LAR) Relationship to Subject

_____ _____
Signature of Legally Authorized Representative Date

Researcher: _____
Printed name of person conducting consent discussion

To be completed by researcher if subject personally signs
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 researcher if subject does not personally sign
I have personally explained the research to the above-named subject's Legally Authorized Representative and answered all questions. I believe that the Legally Authorized Representative understands what is involved in the study and freely agrees to have the subject participate.

I consider that the above-named subject (check one):
☐ is capable of understanding what is involved in the study and freely agrees to participate.
☐ is not capable of understanding what is involved in the study.

_____ _____
Signature of person conducting consent discussion Date