

**BOSTON MEDICAL CENTER
CONSENT TO PARTICIPATE IN the eFHS RESEARCH STUDY**

Electronic Framingham Heart Study (eFHS)

Title of Project: eFHS: eHealth, Mobile Technology and CVD Risk in the Framingham Heart Study

IRB Number: H-36586

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Study Phone Number: (508) 872-6562

eFHS is a medical research study led by Drs. Joanne M. Murabito and Emelia J. Benjamin. These physicians and the Framingham Heart Study staff are available to answer any questions you may have.

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, please feel free to ask the researchers.

Why is this study being done?

The purpose of the eFHS study is to improve our understanding of cardiovascular disease and to find new ways of preventing disease. We will do this by creating questions that you can answer on your mobile phone designed for participants of the Framingham Heart Study.

Am I eligible to participate in the study?

To participate, you must be a member of the Framingham Heart Study. In addition, you need to have an email account with access to a daily internet connection or smartphone.

What will happen if I take part in the eFHS research study?

Surveys

If you agree to participate in eFHS, you will be asked to complete a series of surveys about your life and health using our specially designed App. The surveys will ask about such things as your blood pressure, cholesterol, smoking and other habits, and your history of heart disease, if any. It will take you about 20-30 minutes to get started. Going forward, participation in the study will take about 5-10 minutes per week.

You will be asked to update information on the eFHS surveys every three to six months, or as your health changes.

Health History Updates

We will ask you about your health status every 6 months. We also will create a module within the App that will detect if you enter certain hospitals. Entering a hospital may trigger questions regarding why you were in the hospital. We will use this information to understand how your health changes over time.

Continuing Care Document

You may have access to your Continuing Care Document through your primary care physician's electronic health record. If so, you might be asked to obtain it for eFHS.

Other study activities

As an eFHS participant, you may be invited to participate in additional study activities, or "modules" of the eFHS. The modules may include invitations to use electronic health sensors that measure your blood pressure, weight, physical activity, and heart rhythm. There may be electronic health sensors that measure other aspects of health that become available as the study proceeds that you may be invited to participate in. Participation in additional study modules is optional. That is, you can still be an eFHS participant without participating in additional modules.

If you decide to participate in these additional modules the eFHS app can also pull information from electronic health sensors or apps that you may already be using. To allow for this information to be provided to us, you will need to link these other devices to your eFHS app on your smartphone or other smart devices.

Reminders and study communications

When there is a study activity that we want you to complete or consider, we will contact you. The study will offer a variety of communication options that you can choose from.

How long will I be in the study?

We would like to keep track of your health status for as long as you remain in the study. Keeping in touch with you and checking on your health periodically will help us look at the long-term effects of cardiovascular disease and compare the health of those with and without cardiovascular disease. We plan to contact you on a weekly basis while you are in the study, approximately one year. We will generally contact you directly through the eFHS App.

Can I stop being in the study?

Yes. You can decide to stop at any time. We won't delete the information about you that we have already collected, but we will stop collecting any new eFHS information and will stop contacting you.

To stop participating in the study, please send an email to the study staff at: FHS@bu.edu or call Emily Manders at (508) 935-3443.

What side effects or risks can I expect from being in the study?

Although we will do our best to protect your study information (see below), there is still a very small risk of loss of privacy. There is a risk that participating in the study will make you want to access the healthcare system more often, which costs money. For example, some measures from sensors used in the study may provide information directly to you: for instance a blood pressure monitor may inform you of a high blood pressure reading. An abnormal reading on a sensor might prompt you to want to talk to your health care provider. Whereas there may be benefits to you from seeing your healthcare provider, there are also costs, and the eFHS will not pay for any of your medical care. You should not see your healthcare provider solely for the purpose of collecting data for the eFHS.

For more information about risks and side effects, please ask one of the researchers. You can reach the study coordinator at FHS@bu.edu, Dr. Joanne Murabito at murabito@bu.edu or Dr Emelia Benjamin at emelia@bu.edu Monday to Friday between 9 am and 5 pm. If you want to speak to someone not directly involved in the research study, please contact the Boston University Medical Campus Institutional Review Board at (617) 638-7207.

Are there benefits to taking part in the study?

You will not obtain any direct health benefits from participating in the study, but you may receive information about cardiovascular disease risk factors. We hope that society will benefit from your participation – by participating, you will help us contribute to a better understanding of heart disease and we may find better ways to predict, prevent, and treat heart disease.

Will I get advice about my health from the study?

No. We will not provide you with information about your heart disease or clinical interpretation of your data from the study. **eFHS is a research study and is not clinical care. We do not provide medical services.** Participation in the eFHS does not in any way substitute for professional medical advice, diagnosis, or treatment that your doctor or other healthcare provider may give you. Always ask the advice of your healthcare provider if you have any questions about a medical condition. Do not disregard professional medical advice or delay in seeking care because of something you have read as part of the eFHS study. If you think you may have a medical emergency, please call your doctor or dial 911 immediately.

What other choices do I have if I do not take part in the eFHS study?

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you.

How is my information protected?

We will do our best to make sure that the personal information we collect about you is kept private and secure. **The eFHS will never sell, rent, or lease your contact information.** If information from the eFHS study is published or presented at scientific meetings or shared with other researchers, your name and other personal identifiers will not be used. However, we cannot guarantee total privacy – your personal information may be given out if required by law (e.g., to prevent possible injury to yourself or others).

Your information will be transmitted and stored using very secure systems. We label your samples and information only with a code, and we keep the key to the code in a password protected database. Only approved staff will be 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.**

Once your personal health information is disclosed to others outside the Boston University School of Medicine, it may no longer be covered by federal privacy protection regulations. You can review the privacy policies of the CareEvolution (for study surveys) company here: <https://efhs.careevolution.com/Privacy/eFHS%20Privacy%20Policy.pdf>

What are the costs of taking part in the eFHS study?

You will not be charged to take part in the study. Some of the study components may result in the use of some cellular data.

Will I be paid for taking part in the eFHS study?

You will not be paid for taking part in the eFHS study.

What are my rights if I take part in the eFHS study?

Taking part in the eFHS study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you.

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.

We will tell you about new information or changes in the study that may affect your willingness to continue in the study.

Who can answer my questions about the study?

You can contact eFHS staff through “Contact Us” section of the App or by emailing us directly at FHS@bu.edu.

You may also call 617-638-7207 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.

CONSENT

You can access and print copies of the eFHS consent form whenever you like via the FHS website.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to be in this study, please select the button that says “agree”.