

**RESEARCH CONSENT FORM ADDENDUM
for the eFHS RESEARCH STUDY**

Basic Information

Title of Project: eFHS RCT #2

NCT04752657

IRB Number: H-40737

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

Principal Investigator: Joanne M. Murabito, MD, ScM
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Framingham Heart Study
73 Mount Wayte Ave.,
Framingham, MA 01702

Study Phone Number: (508) 872-6562

Purpose

This is an addendum to the informed consent form that you signed when you joined our study and downloaded the eFHS app. The original consent provided the following information about other study activities:

“As an eFHS participant, you may be invited to participate in additional study activities, or ‘modules’ of the eFHS... You may also be invited to participate in Randomization controlled trials (RCTs) during your eFHS participation.”

What Will Happen in this Research Study

We are now asking for your consent to take part in this eFHS study RCT component. If you agree, you will be randomly assigned (like the flip of a coin) to receive smartphone app surveys and information at different schedules in order to meet study aims. Depending on the random assignment, participants will receive survey modules on either a two-week or a four-week schedule. We are testing different scheduling schemes to understand the effect on overall response rate.

You do not need to agree to participate in this new component of the study; participation is completely voluntary. You can continue to participate in eFHS without agreeing to participate in the randomized controlled trial component. All of the information about the study that is described in the main consent form still applies, and the main consent form can be accessed at the Framingham Heart Study website.

Risks

Although we will do our best to protect your study information, there is still a very small risk of loss of privacy.

Potential Benefits

You will not obtain any direct health benefits from participating in the study. 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.

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 eFHS Study Coordinator at (508) 872-6562. You can also reach the study coordinator at FHS@bu.edu or Dr. Joanne Murabito at murabito@bu.edu Monday to Friday between 9 am and 5 pm.

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.

Please click “Agree” below if you consent to take part in the new randomized messaging component of this study: