

OMB Control Number: 0925-0216

Expiration Date: 10/2016

Public reporting burden for this collection of information is estimated to average 15 or 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0216). Do not return the completed form to this address.

Dear _____:

We thank you for participating in the Framingham Heart Study. Your clinic appointment is scheduled for at _____.

The Framingham Heart Study's address is 73 Mt. Wayte Avenue, in the **Perini Building**. The Framingham Heart Study offices are **located in the wing at the Franklin Street side** of the Building. **There is reserved parking for participants behind the Franklin Street wing**. Please see the enclosed map. The building is handicap accessible.

You should bring slippers and if you choose, bring your own robe. In order to perform certain tests, we ask that you **NOT eat after 8:00 P.M. the previous evening**. You may have **water, decaffeinated black coffee or tea (no creamer, milk or sugar) that evening and again in the morning** before your appointment. A urine sample will be collected when you arrive.

Please do not wear jewelry because of the Bone Density Scan.

Please **take any prescription medications**, as you normally would.

Using the enclosed **MEDICATION BAG**, please bring all prescription and nonprescription medications **you currently take or have taken in the past month in their original containers.**

ON THE BACK OF THIS SHEET, please list information regarding hospitalizations and major illnesses you have experienced since your last exam or health history with the Framingham Heart Study.

PLEASE BRING THIS LETTER WITH YOU TO THE CLINIC. If you need help completing this form, Clinic staff can assist you at the time of your appointment.

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If you have any questions, please call Maureen Valentino, Project Coordinator at **(508) 935-3417** locally and for long distance at **(800) -536-4143**

Sincerely yours,

Daniel Levy,
MD Director
Framingham Heart
Study

OVER →

FHS REPORT GOES TO:

Doctor's Name

Doctor's Address & Phone #

Hospitalizations, Emergency Room Visits, or Day Surgery Since Your Last Clinic Visit

Date

Reason

Hospital Name & Address

Doctor's Name

Doctor Office Visits:

Date

Reason

Doctor's Name

RESEARCH SUBJECT'S AUTHORIZATION

FOR RELEASE OF HEALTH INFORMATION FOR RESEARCH PURPOSES

Name of Research Study: Framingham Heart Study

IRB Number: H-32132

Subject's Name: _____ Birth Date: _____

_____ We want to use your private health information in this

research study. This will include

both information we collect about you as part of this study as well as health information about you that is stored in your medical record. The law requires us to get your authorization (permission) before we can use your information or share it with others for research purposes. You can choose to sign or not to sign this authorization. However, if you choose not to sign this authorization, you will still be able to take part in the research study. Whatever decision you make about this research study will not affect your access to medical care.

Section A:

I authorize the use or sharing of my health information as described below:

Who will be asked to give us your health information:

Who will be able to use your health information for research:

- *The researchers and research staff conducting this study at the Framingham Heart Study*

We may also be asked or required by law to share your health information with the following people if they request it. Once we give it to them, your information is no longer protected under the federal Privacy Rule. However, its use and further disclosures remain limited as stated in your Informed Consent Form as part of BUMC Institutional Review Board oversight.

- *Boston University Medical Center Institutional Review Board*
- *Other governmental agencies that oversee research*



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Section B: Description of information:

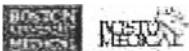
(1) If you choose to be in this study, the research team needs to collect information about you and your health. This will include information collected during the study as well as information from your existing medical records from _____ through _____

(2) Your health information will be used and shared with others for the following study-related purpose(s):

- *Data Analysis of Results*

(3) Specific description of information we will collect:

- Face sheet
- Discharge Summary
- ER Reports
- Admission Notes
- Progress Notes
- Operative Reports
- Pathology Reports
- Echocardiograms
- X-Rays
- EKGs
- EEGs -
- CT Scans
- MRI/MRAs
- Mammograms
- Lab Reports
- Consults
- Cardiac Catheterization Reports
- Exercise Tolerance Tests
- Nursing Home notes
- Notes Near Time of Death
- Arteriography
- PA gram
- Other: For example Venous Ultrasound, V/Q Scan etc.



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Section C: General

(1) Expiration:

- *This authorization expires at the end of the study*

(2) Right To Revoke:

You may revoke (take back) this authorization at any time. To do this, you must ask us the Framingham Heart Study for the names of the Privacy Officers at the institutions where we got your health information. You must then notify those

Privacy Officers in writing that you want to take back your Authorization. If you do, we will still be permitted to use and share the information that we obtained before you revoked your authorization but we will only use and share your information the way the Informed Consent Form says.

- If you revoke this authorization, we may still need to share your health information if you have a bad effect (adverse event) during the research.

(3) Your Access to the Information:

You have the right to see your medical records, but you will not be allowed to review your Framingham Heart Study research record until after the study is completed.

I have read this information, and I will receive a signed copy of this form.

Signature of research subject or personal representative

Date

Printed name of personal representative:

Relationship to research subject:

Please describe the personal representative's authority to act on behalf of the subject:



BUMC/BMC Institutional Review Board
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