OMB#: 0925-0216
Expiration Date: xx/xxxx

«FName» «MName» «LName»«Suffix»
«Str1»
«Str2»
«City», «State» «Zip»

ID#: «ID»

Dear «Prefix» «LName»,

We would like to update the health information that we have on file for you at the Framingham Heart Study. As a participant in the Heart Study, it is important that we have information regarding diagnoses for any significant heart disease, vascular disease, stroke or cancer since we last examined you.

Please complete the enclosed medical history update form. Also, please sign and date the consent form. This procedure will give us permission to obtain the necessary information from the physicians and hospitals where you may have received care. Please inform us if there is any name, address or telephone number change.

If you have questions, please don't hesitate to call Mary Ann Crossen at 1-508-935-3430 or 1-800-854-7582, extension 430.

Thank you for your help.

Sincerely,

Daniel Levy
Director
Framingham Heart Study

I hereby authorize _____
_____

_____

to release to the Framingham Heart Study
73 Mt. Wayte Avenue
Framingham, MA 01702

The following protected health information my medical record.

Patient Name: «FName» «MName» «LName» Date of Birth: «DOB»
Address: «Str1»
«Str2»
«City», «State» «Zip»

Disclose the following information for dates from «Evdate» to present.

- Face Sheet
- Discharge Summary
- ER Report
- Admission Notes
- Progress Notes
- Operative Report
- Pathology Report
- Chest X-Ray
- EKGs (All)
- Echocardiogram
- CT Scan (Head)
- MRI/MRA (Head/Neck)
- Lab Reports – Cardiac Enzymes
- Consults (Cardiac & Neuro)
- Cardiac Catheterization
- Exercise Tolerance Test
- Nursing Home Notes
- Notes near time of death
- Other _____
  _____

The purpose for this disclosure is research.

The information disclosed under this authorization **will not be redisclosed** to anyone but the researchers conducting this study, except as required by law.

I understand I may revoke this authorization at any time by requesting such of the above referenced physician/hospital in writing. If I do it will not have any effect on actions that the hospital/physician took before it received the revocation.

This authorization expires at the end of the research study.

Date: _____ Signed: _____

INSTRUCTIONS:

By signing an Authorization agreement, your research subjects give you permission to use their health information and to share it with others. You will present a copy of this signed agreement to hospitals and care providers when you request medical information about your subjects.

Instructions for completing the form:

On the Authorization form (on following pages), please delete any italicized items that do not pertain to your study. Add new items as necessary. Also delete all of the blue italicized directions.

Non-italicized wording must not be altered . Those statements are required language.

All sections must be completed.

When you fill out Section A, item "Outside places," you will list the names of all facilities from which the subjects medical records will be obtained.

In Section B, describe the information that you are requesting for the research subject and the person/institution from whom you are requesting records. Also in Section B, when you fill out "Specific description of information," you may indicate "entire medical record" or specific items such as specific laboratory tests or imaging studies. You may want to check with the facility holding the records to ensure that your description will be acceptable to their records administrator.

If you have questions, call the IRB office (617-638-7207) or send an email to irbhipaa@bu.edu .
When you have finished, delete this Instructions page and send the completed Authorization form as an email attachment to irbhipaa@bu.edu .
Please type:

- ***"Completed Authorization form" in the subject line of the email***
- ***Your paper-mail address in the body of the email***

We will return the approved form to you so you can use it as part of your informed consent process for all subjects who enroll in your study on or after 4/14/03.

Thank you.

HIPAA-Compliant Medical Record Release form

FOR RELEASE OF HEALTH INFORMATION FOR RESEARCH PURPOSES

Name of Research Study:

Evaluation of Omni Generation II cohort of the Framingham Heart Study

IRB Number: **H-22681**
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*

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

(2) **from _____ through_____**

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

Data Analysis of Results

(2) Specific description of information we will collect:

- ***Face sheet,***
- ***Discharge Summary***
  ER Report
  Admission Notes
  Progress Notes,
  Operative Report
- ***Pathology Report,***
- ***Chest X-Rays***
- ***EKGS***
- ***CT Scan(Head /Heart)***
- ***MRI/MRA (Head/Neck)***
- ***Lab Reports- Cardiac Enzymes***
  Consults (Cardiology & Neurology)
  Cardiac Catheterization
  Exercise Tolerance Test
  Nursing Home notes
  Notes Near Time of Death
  Other (for example: Echocardiogram, Arteriography, Venous Ultrasound, V/Q Scan, PA gram, etc)

Section C: General

Expiration:

This authorization expires at .the end of the study

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.

1. **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.**

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:

_____

_____

OMB#: 0925-0216
Expiration Date: xx/xxxx

For Office Use Only

TYPE |___|___| 1=TELEPHONE 2=MAILER 3=ONSITE BONE STUDY 4=ONSITE EBCT 88=OTHER

INTERVIEWER |___|___|___| DATA ENTRY |___|___|___|1 |___|___|___|2

ID **«ID»**

DATE OF LAST EXAM OR UPDATE **«Evdate»**

NAME **«FName» «MName» «LName»**

ADDRESS and PHONE (if changed since last exam/update) _____

_____

SOCIAL SECURITY NUMBER |___|___|___| - |___|___| - |___|___|___|___|

DATE COMPLETED |___|___| - |___|___| - |___|___|

1. a. First, please tell us who is completing this form:

- ☐ Framingham Heart Study (FHS) participant whose name is above **(Go to question 3)**
- ☐ Spouse
- ☐ Family member other than spouse (Relationship) _____ Go to1.b.
- ☐ Friend
- ☐ Health care provider for FHS participant
- ☐ Other _____

If other than participant, please answer the following questions.

b. Name _____

c. How long have you known the participant?

|___|___| years |___|___| months

d. Are you currently living in the same household with the participant?

☐ yes ☐ no

e. How often did you talk with the participant during the prior 11 months? Check one.

☐ Almost every day
☐ Several times a week
☐ Once a week
☐ 1 to 3 times per month
☐ Less than once a month
☐ Unknown / N/A

2. Have you noticed that he/she has had any memory problems or change in personality?

☐ yes ☐ no

Specifically:

_____

If response to #2 "yes":

Has there been a diagnosis of dementia or Alzheimer's Disease made by a doctor?

☐ yes ☐ no

TO WHOM SHOULD WE SEND A CONSENT FORM TO BE SIGNED SO THAT WE CAN OBTAIN MEDICAL RECORDS?

NAME: _____

ADDRESS: _____

RELATIONSHIP: _____

Please go on to the next page

3. Since the date of the last Framingham Heart Study exam or update on the first page of the Medical History Update form, have you seen a doctor or been hospitalized?

☐ yes ☐ no If yes, did you have any of the following problems?

a. Heart Problems, such as:

Yes No (Mark yes or no for each question)

☐☐ Chest pain, angina or angina pectoris

☐☐ Heart attack or myocardial infarction or MI

☐☐ Heart failure or congestive heart failure or CHF

☐☐ Atrial fibrillation or atrial flutter

☐☐ Heart catheterization or cardiac catheterization

☐☐ Heart bypass operation or coronary bypass surgery or CABG

☐☐ Procedure to unblock narrowed blood vessels to your heart muscles (PTCA, coronary angioplasty, or coronary stent)

☐☐ Other heart problem (pacemaker, valve problem, aorta surgery, ventricular tachycardia, other rhythm problem) Specify

_____

b. Circulatory Problems, such as:

Yes No (Mark yes or no for each question)

☐☐ Stroke, TIA (transient ischemic attack), sudden paralysis, Vision loss, inability to speak

☐☐ Procedure to unblock narrowed blood vessels in your neck (carotid endarterectomy, carotid angioplasty).

☐☐ Poor blood circulation or blocked or narrowed blood vessels to the legs or feet, (claudication, peripheral arterial disease, gangrene)

☐☐ Amputation of part of a leg or toes, because of poor circulation or gangrene.

☐☐ Blood clot or embolism in leg or lung.

☐☐☐ Other circulatory problem.

Specify

_____

Since the date of the last Framingham Heart Study exam or update on the first page of the Medical History Update form, have you seen a doctor or been hospitalized for the following:

c. Other Neurological Problems

Yes No (Mark yes or no for each question)

☐☐☐☐☐ Memory problems

☐☐☐☐☐ Other neurological problems such as Parkinson's, multiple sclerosis, seizures, head injury. Specify problem_____

☐☐☐☐Have you had an MRI scan of your brain other than for the Framingham Heart Study?

Name of MRI Facility

_____

Date of MRI |___|___| - |___|___| - |___|___|

Reason for MRI:_____

d. Other Problems

Yes No (Mark yes or no for each question)

☐☐☐☐Diabetes If yes, please list medications you take for diabetes

_____

☐☐☐ Cancer Specify type

_____

Physician

_____

Place where biopsy performed_____

_____

_____

☐☐☐ Fracture, broken bone (Specify including hip, back, arm, leg, pelvis, collarbone, foot, toe and others)_____

☐☐☐ Other Specify problem

_____

Please go on to the next page

4. Since the date of your last Framingham Heart Study exam or update on the first page of the Medical History Update form, have you been admitted to a **HOSPITAL** or gone to an **EMERGENCY ROOM** or seen a **PHYSICIAN** for other than a routine examination?

☐ yes (if yes, please give details) ☐ no (go to question 5 on the next page)

Date |___|___| - |___|___| - |___|___|

Type* _____ _____

Reason** _____ _____

Hospital Name _____ Doctor's Name

_____

Address _____ Address

_____

_____

_____

Date |___|___| - |___|___| - |___|___|

Type* _____ _____

Reason** _____ _____

Hospital Name _____ Doctor's Name

_____

Address _____ Address

_____

_____

_____

Date |___|___| - |___|___| - |___|___|

Type* _____ _____

Reason** _____ _____

Hospital Name _____ Doctor's Name

_____

Address _____ Address

_____

_____

_____

* Type

1. Overnight admission
2. Emergency room visit
3. Day Surgery/Procedure
4. M.D. visit

** Reason

1. Heart problems
2. Stroke or transient ischemic attack (TIA), sudden paralysis, vision loss, inability to speak
3. Broken, crushed or fractured bones
4. Cancer or malignant tumor
5. Circulation problem, or blood clots
6. Other reasons (Please specify)

Nursing Home/Rehabilitation Admissions.

5. Have you stayed overnight as a patient in a nursing home, rehabilitation center or transitional care unit (TCU) since the date of your last Framingham Heart Study exam or update on the top of the first page of the Medical History Update form?

☐ yes ☐ no (if no, go to Question 8.)

6. Please list the name and location of the nursing home or rehabilitation center and the date
you were admitted.

Nursing home/Rehab Center name:

_____

Street address:

_____

City/State/Zip Code

_____

Date you entered the nursing home/rehabilitation center |___|___| - |___|___| - |___|___|

7. Were you an overnight patient in a nursing home, rehabilitation center or transitional care unit (TCU) at any **other** time since your last exam?

☐ yes ☐ no

Nursing home/Rehab Center name:

_____

Street address:

_____

City/State/Zip Code

_____

Date you entered the nursing home/rehabilitation |___|___| - |___|___| - |___|___|

Marital Status.

8. What is your **current** marital status? Please check one

☐ married ☐ widowed ☐ divorced ☐ separated
☐ single, never married ☐ living with partner

Health Status. (Questions 9 and 10 to be filled out only by the participant.)

9. In general, how is your health now?

☐ Excellent
☐☐☐ Fair
☐ Poor
☐☐☐ Good
☐ Don't know

10. Compare your health to most people your own age. Would you say your health is?

☐ Better
☐ Worse than most people
☐ About the same
☐ Don't know

Primary Care Physician

11. Please list the name and address of your primary care physician.

Name _____

Address _____

_____

YOU MIGHT BE SENT A CONSENT FORM TO SIGN SO THAT WE MAY OBTAIN YOUR MEDICAL RECORDS.