General Hospital Medical Record Dept. 123 Main St. Anytown, MA 00000

To Whom It May Concern:

As part of the research study of the National Heart, Lung and Blood Institute, the Framingham Heart Study has been studying the causes of coronary disease and stroke for nearly fifty years. We are interested in completing our records on the person listed below who has been a participant in our long-term study.

Patient:	Jane Doe	ID# 0- 0	
	000 Main St.		
	Anytown, MA 00000	Date of Birth:	00/00/00

Date(s): Records Requested:

Face Sheet Discharge Summary	CT Scan (Head) MRI/MRA (Head)
ER Report	Lab RptsCardiac Enzymes
Admission Notes	Consults Cardiac & Neuro
Progress Notes	Cardiac Catheterization
Operative Reports	Exercise Tolerance Test
<pre>Pathology Reports</pre>	Nursing Home Notes
Chest X-Rays	Notes near time of death
EKGs (all)	

We would appreciate copies of the records requested. A return envelope is enclosed for your convenience. The information you provide will be kept confidential, and will not be disclosed to anyone but the researchers conducting this study, except as otherwise required by law.

Please use enclosed return envelope or send reply/information To: Attn: MEDICAL RECORDS DEPARTMENT

Thank you for your kind assistance in this matter.

Sincerely yours,

Daniel Levy, M.D. Medical Director Framingham Heart Study

DL/lm

State Dept. of Vital Statistics OMB NO=0925-0216 03-08-2010 123 Main St. Anytown, MA 00000

To Whom It May Concern:

As part of the research study of the National Heart, Lung and Blood Institute in Framingham, Massachusetts into the causes of coronary disease and stroke, we are interested in completing our records on the person listed below who was in our study and had died within your jurisdiction.

Name: John Doe ID# 0- 0 Date of Death: 00/00/00

Date of Birth: 00/00/00

We would appreciate a copy of the death certificate. The information you provide will be kept confidential, and will not be disclosed to anyone but the researchers conducting this study, except as otherwise required by law.

Please use enclosed return envelope or send reply/information to Attn: MEDICAL RECORDS DEPARTMENT

Thank you for your kind assistance.

Sincerely yours,

Daniel Levy, M.D. Medical Director Framingham Heart Study

DL/lm

Jane Smith, M.D.

OMB NO=0925-0216 03-08-

123 Main St. Anytown, MA 00000

2010

Dear Doctor:

As part of the research study of the National Heart, Lung and Blood Institute, the Framingham Heart Program has been studying the causes of coronary disease and stroke for nearly fifty years. We are interested in completing our records on the person listed below who has been a participant in our long-term study.

Patient: John Doe ID# 0- 0 0 Main St Anytown, MA 00000

Date of Birth: 00/00/00

Records pertaining to Date:

We would appreciate copies of the records requested. A return envelope is enclosed for your convenience. The information you provide will be kept confidential, and will not be disclosed to anyone but the researchers conducting this study, except as otherwise required by law.

Please use enclosed return envelope or send reply/information To: Attn: MEDICAL RECORDS DEPARTMENT

Thank you for your kind assistance in this matter.

Sincerely yours,

Daniel Levy, M.D. Medical Director Framingham Heart Study

DL/lm

OMB NO=0925-0216 03-08-2010

## **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 <u>irbhipaa@bu.edu</u>.

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.

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

Thank you.

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

HIPAA-Compliant Medical Record Release form **OMB NO=0925-0216** 03-08-2010

# 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:

0 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.

- 0 Boston University Medical Center Institutional Review Board
- 0 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: