

## RESEARCH CONSENT FORM OMNI Generation I Exam 3

H-24583- EVALUATION OF THE OMNI GENERATION I COHORT OF THE FRAMINGHAM HEART STUDY

---

### Background

The Framingham Heart Study is a long term observational research study designed to identify the **relationship between risk factors, genetics, cardiovascular disease, and other health conditions over time.** In the early 90's, the need to establish a new study reflecting the increasing ethnic/racial diversity of the Framingham community was recognized, and a new group of participants was enrolled. They are the Omni cohort of the Framingham Heart Study. As a member of this group, you are now being asked to take part in a follow-up exam.

### Purpose

The purpose of this research study is to 1) investigate factors related to the development of heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other diseases and health conditions; and 2) examine DNA and its relationship to the risks of developing these diseases and health conditions. This examination does not take the place of a routine medical check up by your physician

### What Happens In This Research Study

You will be one of approximately 520 subjects to be asked to participate in this study.

The research will take place at: Boston University Medical Center.

Your research examination will take place at the Framingham Heart Study facility located at 73 Mount Wayte Avenue in Framingham, MA or other facility/residence.

The Framingham Heart Study Examination takes about 4 hours and includes the following:

#### 1) History

An interview about your past and present medical status including: heart and lung illnesses; hospitalizations; reproductive history; personal and family history; and medical health habits (including diet, prescription, and non-prescription drug use).

#### 2) Measurements and Procedures

A Framingham Heart Study physician will perform a physical examination. You will be asked to participate in standard measurements routinely done in your physician's office such as height, weight, blood pressure (including measurement in both arms and legs), electrocardiogram, and lung function. You will also be asked questions to assess your ability to perform activities of daily living, general daily functioning, and measures of memory and mood.

You will be asked to have the following procedures:

**Electrocardiogram:** The electrocardiogram measures the rate and regularity of your heartbeats.

**Lung function test:** This requires that you breathe in and out of a machine, which measures how well your lungs are working. Some participants, about 25%, will be asked to inhale a bronchodilator medication (Albuterol) used routinely in lung functioning testing, and then to repeat some of the tests.

**Echocardiogram:** This is a picture of your heart using ultrasound waves instead of radiation.

In the event that you may have had a stroke, you will be examined during your hospitalization (if

**RESEARCH CONSENT FORM  
OMNI Generation I Exam 3**

H-24583- EVALUATION OF THE OMNI GENERATION I COHORT OF THE FRAMINGHAM HEART STUDY

---

applicable) and at 3, 6, 12, and 24 months. The examination will include a neurological evaluation and assessment of your ability to perform activities of daily living. If the neurologist believes that you have had a stroke or definite memory problems, you will be asked if you would be willing to have an M.R.I. (Magnetic Resonance Imaging) scan of the brain. If you do decide at that time to undergo the test, it will be arranged by a clinic coordinator. In some instances, you may be asked to return to the clinic for further testing based on information obtained from your examination.

**3) Blood and urine specimens**

A technician will draw a sample of your blood (112ml (cc) or about 7.5 tablespoons) and you will be asked to give a sample of your urine. Both the blood and urine samples will be used for the testing of potential risk factors for the diseases and health conditions under investigation. The blood samples will also be tested for genetic studies.

**Genetic Studies:** You will be asked if a sample of the blood you have donated may be used for the preparation of DNA (genetic material). Neither your name nor Framingham clinic number will appear on the sample. A new security bar code number and the date the specimen is drawn will be the only information on the label. You will not be routinely informed of the results of the research performed upon your genetic blood sample, although genetic tests may be developed as a result of the combined analysis of samples in the Framingham Heart Study.

Data and DNA will be distributed to Framingham Heart Study researchers and other qualified researchers interested in the genetics of heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, joint disease, bone loss, deafness, cancer, and other diseases and health conditions. The researchers will be given the DNA without any potentially identifying information. Information gained from research on your DNA may be used for the development of diagnostic procedures or new treatments for major diseases. Your DNA will not be sold to any person, institution, or company for financial gain or commercial profit. However, neither you nor your heirs will gain financially from discoveries made using the information and/or specimens that you provide.

**4) Vascular function testing**

You will be asked to participate in three experimental tests of vascular function, which will take about 45 minutes:

- a. Carotid ultrasound takes pictures of the arteries in your neck using sound waves. This involves moving an electronic device across the surface of the neck.
- b. Arterial tonometry tests blood vessel (artery) stiffness by carefully recording the blood pressure waveform. A technician will perform the arterial waveform evaluation using a tonometer (a flat pressure sensor which, when pressed lightly on the skin over the artery, records a waveform). The blood vessels in the neck (carotid), arm (brachial and radial), and groin (femoral) will be studied by tonometry.
- c. Fingertip pulse test. The technician will measure the pulse at a fingertip in each hand at baseline, after blood pressure cuff inflation and after release of the blood pressure cuff.

**5) Medical Records**

You will be asked to sign a medical release form to allow the Framingham Heart Study Medical Records

## RESEARCH CONSENT FORM OMNI Generation I Exam 3

H-24583- EVALUATION OF THE OMNI GENERATION I COHORT OF THE FRAMINGHAM HEART STUDY

---

staff to obtain and review copies of your hospital, cancer registry, and medical records for the Framingham Heart Study Physician Review. This medical release will be considered valid to obtain these records and this authorization will be valid until canceled by you.

With your permission, a summary letter of routine test results from this exam will be sent to you and your physician.

You will be contacted about every two years to obtain additional health information. You may also be contacted to determine your interest in participating in other FHS health-related studies. You will be asked to give your social security number for the purpose of locating you in the future, which will be up to you. It is expected that this exam will be done approximately every 4 to 8 years at which time you will be asked to sign a new consent form. If an exam is not possible, you may be asked to complete a medical history update over the phone.

You may choose to withdraw your blood samples at a future date and your samples will be destroyed at that time. If you choose to withdraw your samples, you should call the Framingham Heart Study at (508) 935-3477 and ask for the lab manager.

Any questions you have regarding your rights as a research subject can be directed to the Office of the Institutional Review Board for Boston Medical Center at (617) 638-7207. The Framingham Heart Study is a medical research project sponsored by the National Institutes of Health. It is authorized under 42USC 285b-3. The system of records which applies to the Framingham Heart Study is documented in the Federal Register, September 26, 2002 (Vol. 67, No. 1879) pages 60776-60780.

### Risks and Discomforts

Each of the test procedures and their risks and discomforts are listed below:

**The Carotid Ultrasound Test:** This procedure is painless. Ultrasound is widely used in clinical applications because of its low risk. Your exposure to ultrasound in this examination will be no greater than a typical clinic exam.

**Fingertip pulse test:** The main risks are tingling, or mild pain and painless red spots (petechiae). About 0.5% of participants who have the PAT test develop painless red spots after the test on the same arm; the red spots go away after a few days without any treatment. The fingertip device is made of latex and may cause a reaction if you have a latex allergy. Please tell us if you have an allergy to latex and we will not apply the fingertip device.

**Echocardiogram:** There may be mild discomfort where the transducer is applied.

**The Lung Function Test:** This involves a very low level of risk. On rare occasions a person taking a lung function test may feel lightheaded or may faint. The primary risk involved is injury from falling. Participants asked to inhale the medication called albuterol, used during lung function testing, may notice an increase in heart rate (pulse) or symptoms of jitteriness or shakiness (tremors).

**RESEARCH CONSENT FORM**  
**OMNI Generation I Exam 3**

H-24583- EVALUATION OF THE OMNI GENERATION I COHORT OF THE FRAMINGHAM HEART STUDY

---

**The Blood Draw:** Minimal bruising, pain, or bleeding may occur as a result of the blood draw. In rare circumstances, an infection from a blood draw has been known to occur. A latex allergy can occur from the gloves worn by the technician. If you have a known latex allergy, inform the technician and he/she will use another form of protection.

We do not expect an unusual risk or injury to occur as a result of participation. There are no known risks if you are, or may become pregnant. In the unlikely event that during examination procedures you should require medical care, first aid will be available.

There may be unknown risks/discomforts involved. Study staff will update you in a timely way on any new information that may affect your health, welfare, or decision to stay in this study.

**Potential Benefits**

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand the precursors, etiology, and prevention of cardiovascular disease and other health conditions, including the possibility of genetic linkages.

**Alternatives**

Your alternative is to not participate in the study.

**Subject Costs and Payments**

You will not be charged for any part of the examination. If the examination uncovers any medical problems that require medical diagnosis or treatment, you will be so advised and that information will be provided to the physician or clinic that you choose.

In the event that your physician decides that follow up clinical tests or treatments are necessary, payment must be provided by you or your third party payer, if applicable (for example, health insurance or Medicare). No special arrangements will be made by the Framingham Heart Study for compensation or for payment of treatment solely because of your participation in this study. This does not waive any of your legal rights.

Costs that you might incur the day of your participation include, but are not limited to, loss of work, and transportation (gas, tolls, etc.). You will not receive payment for your participation.

**Confidentiality**

Any information we obtain about you during this study will be treated as strictly confidential to the full extent permitted by applicable law. To ensure confidentiality, a code number will be assigned to you and any of your potentially identifying information.

The code number will not be used on any blood samples you provide. A label with a new security bar code number and the date the specimen is drawn will be the only information on the label. The code numbers will only be provided to qualified investigators studying the DNA samples. Files linking names to samples will be kept locked and accessible only to Framingham Heart Study data managers. The coded samples will be stored securely, separated from files which link your name to the code numbers.

OMNI Generation I Exam 3  
Res. v5

**RESEARCH CONSENT FORM  
OMNI Generation I Exam 3**

H-24583- EVALUATION OF THE OMNI GENERATION I COHORT OF THE FRAMINGHAM HEART STUDY

---

Without your specific authorization, no other individuals will have access to the stored sample or information gained from your stored sample. No genetic information from the analysis of these samples will be provided to you or to others without your authorization, therefore the risk in providing this sample is minimal. Your sample will be kept until it is no longer of scientific value.

When study results are published, your name and any other potentially identifying information (i.e. code number) will not be revealed. You will be kept informed through periodic publications from the Framingham Heart Study of any new findings about genetics, cardiovascular disease or other health conditions generated from the DNA analyses.

Information from this study and from your medical record may be reviewed and photocopied by the Food and Drug Administration (FDA) and/or state and federal regulatory agencies such as the Office of Human Research Protection as applicable, and the Institutional Review Board of Boston University Medical Center.

Please check the appropriate box beside each statement you agree with:

- 1)  IYES  INO I agree to participate in the Framingham Heart Study examinations described above to study the frequency of and factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, and other diseases and health conditions.
- 2)  IYES  INO I agree to provide a blood sample from which DNA and other components can be extracted. The DNA will be made available to researchers studying the diseases listed above.
- 3)  IYES  INO I agree to participate in the genetic studies of factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, and memory loss.
- 4)  IYES  INO I agree to participate in genetic studies of other diseases and health conditions including but not limited to joint disease, bone loss, and cancer.
- 5)  IYES  INO I agree to participate in genetic studies of reproductive conditions and mental health conditions such as alcohol use and depressive symptoms.
- 6)  IYES  INO I agree to allow researchers from private companies to have access to my DNA and genetic data which may be used to develop diagnostic lab tests or pharmaceutical therapies that could benefit many people. (Note: You or your heirs will not benefit financially from this, nor will your DNA be sold to anyone.)
- 7)  IYES  INO I agree to allow the Framingham Heart Study to release the findings from non-genetic tests and examinations to my physician, clinic, or hospital.
- 8)  IYES  INO If a genetic condition is identified that may have potentially important health and treatment implications for me, I agree to allow the Framingham Heart Study to notify me and, with my

OMNI Generation I Exam 3  
Res. v5

**RESEARCH CONSENT FORM**  
**OMNI Generation I Exam 3**

H-24583- EVALUATION OF THE OMNI GENERATION I COHORT OF THE FRAMINGHAM HEART STUDY

---

treatment implications for me, I agree to allow the Framingham Heart Study to notify me and, with my permission, to notify my physician.

**Subject's Rights**

By consenting to participate in this study you do not waive any of your legal rights. Giving consent means that you have heard or read the information about this study and that you agree to participate. You will be given a copy of this form to keep. If at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled.

You may obtain further information about your rights as a research subject by calling the Office of the Institutional Review Board of Boston University Medical Center at 617-638-7207.

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, or if you need to report an injury while participating in this research, contact Dr. Emelia J. Benjamin or Dr. Daniel Levy at 508 872 6562  
The Framingham Heart Study, 73 Mount Wayte Avenue, Suite #2, Framingham, MA 01702

**Compensation for Research Related Injury**

If you think that you have been injured by being in this study, please let the investigator know right away. If your part in this study takes place at Boston Medical Center, you can get treatment for the injury at Boston Medical Center. If your part in the study is not at Boston Medical Center, ask the investigator where treatment for injury would be available locally. You and your insurance company will be billed for this treatment. Some research sponsors may offer a program to cover some of the treatment costs which are not covered by your insurance. You should ask the research team if such a program is available.

**Right to Refuse or Withdraw**

Taking part in this study is voluntary. You have the right to refuse to take part in this study. If you decide to be in the study and then change your mind, you can withdraw from the research. Your participation is completely up to you. Your decision will not affect your being able to get health care at this institution or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

If you choose to take part, you have the right to stop at any time. If there are any new findings during the study that may effect whether you want to continue to take part, you will be told about them as soon as possible.

The investigator may decide to discontinue your participation without your permission because he/she may decide that staying in the study will be bad for you, or the sponsor may stop the study.

**RESEARCH CONSENT FORM**  
**OMNI Generation I Exam 3**

H-24583- EVALUATION OF THE OMNI GENERATION I COHORT OF THE FRAMINGHAM HEART STUDY

---

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

\_\_\_\_\_  
Subject (Signature and Printed Name)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Person Obtaining Consent (Signature and Printed Name)

\_\_\_\_\_  
Date