

RESEARCH CONSENT FORM OMNI Generation II Exam 1

H-22681- EVALUATION OF THE OMNI GENERATION II 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 most recent and diverse community of Framingham was recognized, and a new group of participants was enrolled. They are the Omni cohort of the Framingham Heart Study. We are now entering a new phase of the study and enrolling an additional group of Omni participants. You are invited to participate in this research study.

Purpose

The specific purpose of this research study is to 1) investigate factors related to the development of 1)heart and blood vessel diseases, lung and blood diseases, stroke, cancer, and other health conditions; and to 2) examine vascular function and its relationship to risk 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 410 subjects to be asked to participate in this study.

The research will take place at the following location(s): Boston University Medical Center.

Your examination will take place at 73 Mt. Wayte Avenue 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: past and present heart and lung illnesses; hospitalizations; reproductive history; personal and family history; general 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, and blood pressure, electrocardiogram, and lung function. You will also be asked to have procedures such as an echocardiogram and vascular testing. (See below for further descriptions)

Electrocardiogram: The electrocardiogram measures the rate and regularity of your heart beats.

Lung function test: This requires that you breathe in and out of a machine, which measures how well your lungs are working.

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 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

OMNI Generation II Exam 1

RESEARCH CONSENT FORM
OMNI Generation II Exam 1

H-22681- EVALUATION OF THE OMNI GENERATION II COHORT OF THE FRAMINGHAM HEART STUDY

be arranged by the clinic coordinator and you will be asked to sign a separate consent form. 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 (112.5 cc or about 7.5 tablespoons) and you will be asked to give a sample of your urine. Both the blood and the urine samples will be used for the testing of potential risk factors for the diseases and health conditions that are under investigation. The blood samples may also be tested for genetic studies. Included in our blood analysis will be a measurement of cholesterol values, triglycerides, and glucose. Results of these tests will be given to both you and your physician.

Genetic Studies: You will be asked if a sample of the blood you donate (40 cc or about 3 tablespoons) can be used for the preparation of DNA. 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.

Data and DNA will be distributed to researchers conducting the Framingham Heart Study and other qualified researchers interested in the genetics of heart, lung and blood diseases and other diseases and health conditions. The scientists from these laboratories 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 anyone or to institutions or companies for financial gain or commercial profit without your consent. 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 tests of vascular function, which will take about 30-40 minutes:

a. Brachial ultrasound measures the ability of a blood vessel in your arm (brachial artery) to get bigger (dilate) when exposed to increased blood flow; this measures the health of the blood vessel lining. A technician will perform brachial ultrasound before, during and after 5 minutes of blood pressure cuff inflation on your lower arm.

b. Fingertip pulse test. While the technician is performing the ultrasound test, he/she will also measure your pulse at a fingertip on each hand.

c. 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.

5) Medical Records.

OMNI Generation II Exam 1

RESEARCH CONSENT FORM OMNI Generation II Exam 1

H-22681- EVALUATION OF THE OMNI GENERATION II COHORT OF THE FRAMINGHAM HEART STUDY

You will be asked to sign a medical release form to allow the Framingham Heart Study Medical Records staff to obtain and review copies of your hospital, cancer registry, and medical records for Framingham Heart Study Physician Review. This medical release form will be considered as valid to obtain these records, and this authorization will remain valid until canceled by you.

You may be contacted later to obtain additional health information, or 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. You may be asked to come back for another exam in the future, 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.

A summary letter of routine test results from this exam will be sent to you and your physician.

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 have been listed below:

The Brachial Ultrasound Test: The main risks are tingling, or mild pain and painless red spots (petechiae). About 0.5% of participants who have the brachial ultrasound 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 Pulse Test: The fingertip device is made of latex and may cause a reaction if you have an allergy to latex. Please tell us if you have a latex allergy and we will not apply the fingertip device.

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.

The Blood Draw: Minimal bruising may occur as a result of the blood draw. A latex allergy can occur from the gloves worn by the technicians. 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. In the unlikely event that, during examination procedures, you should require medical care, first aid will be available. There may also be some risks that are unforeseeable. Framingham Heart Study Investigators will tell you if new

OMNI Generation II Exam 1

RESEARCH CONSENT FORM
OMNI Generation II Exam 1

H-22681- EVALUATION OF THE OMNI GENERATION II COHORT OF THE FRAMINGHAM HEART STUDY

information becomes available that may affect your willingness to participate.

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 frequency, causes (risk factors), and consequences of cardiovascular disease..

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 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 II Exam 1

RESEARCH CONSENT FORM
OMNI Generation II Exam 1

H-22681- EVALUATION OF THE OMNI GENERATION II COHORT OF THE FRAMINGHAM HEART STUDY

You will not be 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.

No other individuals will have access to the stored sample or information gained from your stored sample. **Because no information will be provided to you or to others from the analysis of this sample, the risk in providing this sample is minimal. Your sample will be kept until it is no longer of scientific value.**

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. Information from this study and from your medical record may be used for research purposes and may be published; however, your name will not be used in any publications. 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.

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

I YES I NO

I agree to participate in the physical examination and genetic studies of factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, joint disease, bone loss, deafness, cancer, and other major diseases and health conditions.

I YES I NO

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.

I YES I NO

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.)

I YES I NO

I agree to allow the Framingham Heart Study to release the findings from tests and examinations to my physician, clinic, or hospital.

RESEARCH CONSENT FORM
OMNI Generation II Exam 1

H-22681- EVALUATION OF THE OMNI GENERATION II COHORT OF THE FRAMINGHAM HEART STUDY

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**. If this study is being done outside the United States you can ask the investigator for contact information for the local Ethics Board.

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 Benjamin (617 638 8968) or Dr. Daniel Levy (508 872 6562) at the Framingham Heart Study, 73 Mount Wayte Avenue, Suite #2, Framingham, MA 01702. After office hours you may page Dr. Benjamin by calling 617 638 8000.

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

OMNI Generation II Exam 1

RESEARCH CONSENT FORM
OMNI Generation II Exam 1

H-22681- EVALUATION OF THE OMNI GENERATION II COHORT OF THE FRAMINGHAM HEART STUDY

may decide that staying in the study will be bad for you, or the sponsor may stop the 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

RESEARCH CONSENT FORM
Omni Generation II Exam 1 - Consent by Substituted Judgment

H-22681- EVALUATION OF THE OMNI GENERATION II COHORT OF THE FRAMINGHAM HEART STUDY

Background

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What Happens In This Research Study

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All or part of the research in this study will take place at the following location(s): Boston University Medical Center.

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Omni Generation II Exam 1 - Consent by Substituted Judgment

RESEARCH CONSENT FORM

Omni Generation II Exam 1 - Consent by Substituted Judgment

H-22681- EVALUATION OF THE OMNI GENERATION II COHORT OF THE FRAMINGHAM HEART STUDY

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4) Vascular function testing.

You will be asked to participate in three tests of vascular function, which will take about 30-40 minutes:

- a. **Brachial ultrasound** measures the ability of a blood vessel in your arm (brachial artery) to get bigger (dilate) when exposed to increased blood flow; this measures the health of the blood vessel lining. A technician will perform brachial ultrasound before, during and after 5 minutes of blood pressure cuff inflation on your lower arm.
- b. **Fingertip pulse test.** While the technician is performing the ultrasound test, he/she will also measure your pulse at a fingertip on each hand.
- c. **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.

5) Medical Records.

Omni Generation II Exam 1 - Consent by Substituted Judgment

RESEARCH CONSENT FORM
Omni Generation II Exam 1 - Consent by Substituted Judgment

H-22681- EVALUATION OF THE OMNI GENERATION II COHORT OF THE FRAMINGHAM HEART STUDY

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You may be contacted later to obtain additional health information, or 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. You may be asked to come back for another exam in the future, 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.

A summary letter of routine test results from this exam will be sent to you and your physician.

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.

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Note that if the participant is unable to adequately understand this Informed Consent Form or is unable to sign the form, consent to his/her participation in this research study may be given by someone else as appropriate. This might occur because the participant suffers from a severe illness or for some other reason. Signature of this form by someone else other than the participant means that:

- a. The person signing and/or the Framingham Heart Study staff or health care professional(s) involved with treating the participant have made a judgment that the participant is unable to adequately understand the Informed Consent Form or is unable to sign the form, and
- b. The person signing the form believes that the participant would have signed the form to give his/her informed consent to participate in this research study were he/she able to do so.

Risks and Discomforts

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

The Brachial Ultrasound Test: The main risks are tingling, or mild pain and painless red spots (petechiae). About 0.5% of participants who have the brachial ultrasound 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 Pulse Test: The fingertip device is made of latex and may cause a reaction if you have an allergy to latex. Please tell us if you have a latex allergy and we will not apply the fingertip device.

Omni Generation II Exam 1 - Consent by Substituted Judgment

RESEARCH CONSENT FORM
Omni Generation II Exam 1 - Consent by Substituted Judgment

H-22681- EVALUATION OF THE OMNI GENERATION II COHORT OF THE FRAMINGHAM HEART STUDY

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.

The Blood Draw: Minimal bruising may occur as a result of the blood draw. A latex allergy can occur from the gloves worn by the technicians. 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. In the unlikely event that, during examination procedures, you should require medical care, first aid will be available. There may also be some risks that are unforeseeable. Framingham Heart Study Investigators will tell you if new information becomes available that may affect your willingness to participate.

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 frequency, causes (risk factors), and consequences of cardiovascular disease..

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 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

Omni Generation II Exam 1 - Consent by Substituted Judgment

RESEARCH CONSENT FORM

Omni Generation II Exam 1 - Consent by Substituted Judgment

H-22681- EVALUATION OF THE OMNI GENERATION II COHORT OF THE FRAMINGHAM HEART STUDY

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.

You will not be 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.

No other individuals will have access to the stored sample or information gained from your stored sample. Because no information will be provided to you or to others from the analysis of this sample, the risk in providing this sample is minimal. Your sample will be kept until it is no longer of scientific value.

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. Information from this study and from your medical record may be used for research purposes and may be published; however, your name will not be used in any publications. 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.

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

YES NO

I agree to participate in the physical examination and genetic studies of factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, joint disease, bone loss, deafness, cancer, and other major diseases and health conditions.

YES NO

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.

YES NO

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.)

YES NO

I agree to allow the Framingham Heart Study to release the findings from tests and examinations to my physician, clinic, or hospital.

Omni Generation II Exam 1 - Consent by Substituted Judgment

RESEARCH CONSENT FORM

Omni Generation II Exam 1 - Consent by Substituted Judgment

H-22681- EVALUATION OF THE OMNI GENERATION II COHORT OF THE FRAMINGHAM HEART STUDY

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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 Benjamin (617 638 8968) or Dr. Daniel Levy (508 872 6562) at the Framingham Heart Study, 73 Mount Wayte Avenue, Suite #2, Framingham, MA 01702. After office hours you may page Dr. Benjamin by calling 617 638 8000.

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.

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Omni Generation II Exam 1 - Consent by Substituted Judgment

RESEARCH CONSENT FORM
Omni Generation II Exam 1 - Consent by Substituted Judgment

H-22681- EVALUATION OF THE OMNI GENERATION II COHORT OF THE FRAMINGHAM HEART STUDY

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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.

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