RESEARCH CONSENT FORM

Offspring Exam 8

H-22762– THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

Background

You are being asked to participate in the 8th Framingham Heart Study Offspring examination. This is an observational study designed to identify the relationship between risk factors, genetics, cardiovascular disease, and other health conditions.

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.

THIS EXAMINATION DOES NOT TAKE THE PLACE OF A ROUTINE MEDICAL EXAMINATION BY YOUR PHYSICIAN.

Taking part in this study is voluntary. You have the right to refuse to take part in this study. If you choose to take part, you have the right to stop at any time.

What Happens In This Research Study

You will be one of approximately 3800 subjects to be asked to participate in this study.

All or part of the research in this study will take place at the following location(s): 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

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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 1000 or 25%, will be asked to inhale a bronchodilator medication (Albuterol) used routinely in lung functioning testing, and then to repeat some of the tests.

3) Blood and urine specimens

A technician will draw a sample of your blood (112 cc(ml) 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 (16 cc or about 1 Tablespoon) may be used for the preparation of DNA (genetic material) and for the creation of a cell line. A cell line is a frozen sample of specially processed white cells from your blood that allows us to grow more white cells and get more DNA from them in future as needed for research projects. Cell lines will be stored at a central site (repository). 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 an experimental tests of vascular function, which will take about 45 minutes:

a. 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

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 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.

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 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.

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.

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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 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).

The Blood Draw: Minimal bruising, pain, bleeding, or in rare circumstances, an infection may occur as a result of the blood draw. 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.

Possible general discomforts include: headaches or feeling hungry if you have not eaten before the exam; fatigue or chill during long exam; communication limitations before, during, or after exam.

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

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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

There are no costs to you for participating in this research study. You will not be paid to participate in this research study.

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 your potentially identifying information.

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.

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Because only limited 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.

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 analysis.

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.

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

1) |___|YES |___|NO 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) |___|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.

3) |___|YES |___|NO If a cell line has not already been collected, I agree to allow a cell line to be made from a sample of my blood to provide a renewable supply of DNA. (A cell line is a frozen sample of specially processed white cells from your blood that allows us to grow more white cells and get more DNA from them in the future as needed for research projects).

4) |___|YES |___|NO 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.

5) |___|YES |___|NO I agree to participate in genetic studies of other diseases and health conditions including but not limited to joint disease, bone loss, and cancer.

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6) |___|YES |___|NO I agree to participate in genetic studies of reproductive conditions and mental health conditions such as alcohol use and depressive symptoms.

7) |___|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.)

8) |___|YES |___|NO I agree to allow the Framingham Heart Study to release the findings from non-genetic tests and examinations to my physician, clinic, or hospital.

9) |___|YES |___|NO 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 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. 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 PHILIP WOLF at (617) 638-5450

Compensation for Research Related Injury

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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 of the study is not at Boston Medical Center, ask the investigator where treatment for injury would be available locally. Boston University Medical Center and the sponsor do not offer a program to provide compensation for the cost of care for research related injury or other expenses such as lost wages, disability, pain, or discomfort. You will be sent a bill for the medical care you receive for research injury if your medical insurance does not pay for your medical care. You are not giving up any of your legal rights by signing this form.

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 affect 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.

Protection of Subject Health Information

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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

_____

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Legally Authorized Representative (LAR) (Signature and Printed Name) Date

_____

Person Obtaining Consent (Signature and Printed Name) Date