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Please use this version to review data inputted in Section Q. To print, click print from your browser toolbar. If you are a PI and need the consent form(s) for subject signature, or you are a reviewer and need to review the consent form(s), click here for the printer friendly version.

RESEARCH CONSENT FORM
Cohort Exam 30

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

Background
You are asked to participate in the 29th Framingham Heart Study examination. This is an observational research 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 physical examination by your physician.

What Happens In This Research Study
You will be one of approximately 440 subjects to be asked to participate in this study.

The research 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 Mt. Wayte Avenue in Framingham, MA. The examination will take approximately 2.5 hours and will include the following:

1) History
An interview about your medical status including: heart and lung illnesses, hospitalizations, emergency room visits, day surgeries, physician visits, and medical health habits (including diet, prescription, and non-prescription drug use).

2) Measurements and Procedures
You will be asked to participate in standardized measurements routinely done in your physician's office such as height, weight, blood pressure and electrocardiogram. The electrocardiogram measures the rate and regularity of your heartbeats. You will be asked questions to assess your ability to perform activities of daily living, general daily function, measures of memory and mood and questions about your social support. You will also be asked questions about your leisure time activities and health care preferences.

You will also be asked to perform tasks to assess your walk, balance, and hand grip strength. This is called Observed Physical Performance.

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 the 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 Specimen
A technician will draw a sample of your blood (20 cc or about 1 Tablespoon) and use currently obtained or previously frozen samples (if applicable) of blood for testing of potential risk factors for the diseases and health conditions under investigation. The blood samples will also be tested for genetic studies.

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 major 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) 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 Framingham Heart Study physician review. This medical release form 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 every 1-2 years to obtain additional health information. You may also be contacted to obtain determine your interest in participating in other FHS health-related studies. It is expected that this exam will be done approximately every 1-2 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.

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 Blood Draw: Minimal bruising, pain, or bleeding 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.
Observed Physical Performance: This test involves a very low level of risk. The primary risk involved is injury from falling.

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 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 cause and prevention of cardiovascular disease and other health conditions, including the possibility of how genetic factors influence health status.

Alternatives
There are no alternative treatments or procedures to participating in this study. You may, however, choose not to participate.

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, transportation costs (gas, tolls, etc). You will not receive payment for your participation. However, if necessary, we will provide transportation to the clinic and your return home at no cost.

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.

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.

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) |___| YES |___| NO I agree to participate in the Framingham Heart Study examination 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 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.)

4) |___| 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.

5) |___| 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 signing this form you do not waive any of your legal rights. Signing this consent form 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 signed form to keep.

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 and/or his/her designee 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 related to the research, contact PHILIP WOLF at (508) 872-6562.

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.

Cohort - Exam 30
Res.v8

RESEARCH CONSENT FORM
Cohort Exam 30 - Offsite

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

Background
You are asked to participate in the 29th Framingham Heart Study examination. This is an observational research 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, joint disease, bone loss, deafness, cancer, and other major 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 physical examination by your physician.

What Happens In This Research Study
You will be one of approximately 440 subjects to be asked to participate in this study.

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

Your research examination will take place at either your residence or the facility where you reside. The examination will take approximately 2 hours and will include the following:

1) History
An interview about your medical history since your last exam or health history update including heart and lung illnesses, hospitalizations, emergency room visits, day surgeries, physicals, and medical health habits (including diet, prescription, and non-prescription drug use).

2) Measurements and Procedures
You will be asked to participate in standardized measurements routinely done in your physician's office such as height, weight, blood pressure, and electrocardiogram. The electrocardiogram measures the rate and regularity of your heartbeats. You will be asked questions to assess your ability to perform activities of daily living, general daily function, measures of memory and mood, and questions about your social support. You will also be asked questions about your leisure time activities and healthcare preferences.

You will also be asked to perform tasks to assess your walking ability, balance, and hand grip strength. This is called Observed Physical Performance.

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 the clinic coordinator. In some instances, you may be asked to come to the clinic for further testing based on information obtained from your examination.

3) Blood Specimen
You will not be asked to provide a blood sample at this visit, although we will use previously frozen blood samples for testing of potential risk factors for the diseases and health conditions under investigation. The blood samples will also be tested for genetic studies.

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 major 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) 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 Framingham Heart Study physician review. This medical release form 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 1-2- years to obtain additional health information. You may also be contacted to determine your interest in participating in other FHS health-related studies. It is expected that this exam will be done approximately every 1-2 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.

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:

Observed Physical Performance: This test involves a very low level of risk. The primary risk involved is injury from falling.

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 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 cause and prevention of cardiovascular disease and other health conditions, including the possibility of genetic factors.
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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.

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 was not be used on any blood samples you provided. 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 are kept locked and accessible only to Framingham Heart Study data managers. The coded samples are 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 keeping 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 that you agree with:

1) |___| YES |___| NO I agree to participate in the Framingham Heart Study examination 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 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.)

3) |___| 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.

4) |___| 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 (508) 872-6562

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.

Cohort Exam 30 - Offsite
Res.v9

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RESEARCH CONSENT FORM
Generation III Exam 2

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

Background

The Framingham Heart Study is an observational study designed to identify the relationship between risk factors, genetics, cardiovascular disease, and other health conditions over three generations. As a person who has at least one parent in the Framingham Heart Study, you are invited to participate.

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, joint disease, bone loss, deafness, cancer, and other major 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 4100 subjects to be asked to participate in this study.

The research 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 Mt. Wayte Avenue in Framingham, MA or other facility/residence. The examination will take approximately 4 hours and will include 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, 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 heartbeats.

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 be arranged by the 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 (112.5 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 (40 cc or about 3 tablespoons) may be used for the preparation of DNA (genetic material) and for the creation of a living tissue sample (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.

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 major 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 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 measures your pulse at a fingertip on each hand while the technician is performing the ultrasound test.
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
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 is considered valid to obtain these records, and this authorization will be 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.

With your permission, 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 are 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. If you have a known latex allergy, inform the technician and he/she 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, pain, or bleeding 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
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.

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.

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) |___| 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.

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 I agree to allow the creation of a cell line from my blood sample.

4) |___| 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.)

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

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 (508) 872-6562.

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.

Generation III Exam 2
Res.v1

RESEARCH CONSENT FORM
Generation III Exam 2 - Consent by Substituted Judgment

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

Background
The Framingham Heart Study is an observational study designed to identify the relationship between risk factors, genetics, cardiovascular disease, and other health conditions over three generations. As a person who has at least one parent in the Framingham Heart Study, you are invited to participate.

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, joint disease, bone loss, deafness, cancer, and other major 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 4100 subjects to be asked to participate in this study.

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

Your research examination will take place either at the Framingham Heart Study facility located at 73 Mt. Wayte Avenue in Framingham, MA or other facility/residence. The examination will take approximately 4 hours and will include 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, 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 heartbeats.

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 be arranged by the 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 (112.5 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 (40 cc or about 3 tablespoons) may be used for the preparation of DNA (genetic material) and for the creation of a living tissue sample (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.

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 major 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 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 measures your pulse at a fingertip on each hand while the technician is performing the ultrasound test.
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
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 is considered valid to obtain these records, and this authorization will be 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.

With your permission, 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.

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 are 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. If you have a known latex allergy, inform the technician and he/she 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, pain, or bleeding 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.

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.

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.

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) |___| 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.

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 I agree to allow the creation of a cell line from my blood sample.

4) |___| 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.)

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

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 (508) 872-6562

Compensation for Research Related Injury
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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.

Background
The Framingham Heart Study is an observational research study designed to identify the relationship between risk factors, genetics, cardiovascular disease, and other health conditions. As a person who has or had a spouse and at least two children in the Framingham Heart Study, you are invited to participate.

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, memory loss, joint disease, bone loss, deafness, cancer, and other major 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 500 subjects to be asked to participate in this study.

The research 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 Mt. Wayte Avenue in Framingham, MA or other facility/residence. The examination will take approximately 4 hours and will include 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; general function; tests of memory and mood; 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, 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 heartbeats.
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.

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 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 (40 cc or about 3 tablespoons) may be used for the preparation of DNA (genetic material) and for the creation of a living tissue sample (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.

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 major 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 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 measures your pulse at a fingertip on each hand while the technician is performing the ultrasound test.
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
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 is considered valid to obtain these records, and this authorization will be 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.

With your permission, 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 are 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. If you have a known latex allergy, inform the technician and he/she 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, pain, or bleeding 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.

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 medical 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.

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.

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) |___| 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.

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 I agree to allow the creation of a cell line from my blood sample.

4) |___| 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.)

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

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 (508) 872-6562

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.

New Offspring Spouse Exam 2
Res.v1

RESEARCH CONSENT FORM
New Offspring Spouse Exam 2 - Consent by Substituted Judgment

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

Background
The Framingham Heart Study is an observational research study designed to identify the relationship between risk factors, genetics, cardiovascular disease, and other health conditions. As a person who has or had a spouse and at least two children in the Framingham Heart Study, you are invited to participate.

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, memory loss, joint disease, bone loss, deafness, cancer, and other major 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 500 subjects to be asked to participate in this study.

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

Your research examination will take place either at the Framingham Heart Study facility located at 73 Mt. Wayte Avenue in Framingham, MA or other facility/residence. The examination will take approximately 4 hours and will include 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; general function; tests of memory and mood; 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, 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 heartbeats.

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

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 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 (40 cc or about 3 tablespoons) may be used for the preparation of DNA (genetic material) and for the creation of a living tissue sample (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.

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 major 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 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 measures your pulse at a fingertip on each hand while the technician is performing the ultrasound test.
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

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 is considered valid to obtain these records, and this authorization will be 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.

With your permission, 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.

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 are 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. If you have a known latex allergy, inform the technician and he/she 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, pain, or bleeding 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.

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 medical 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.

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.

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) |___| 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.

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 I agree to allow the creation of a cell line from my blood sample.

4) |___| 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.)

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

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 (508) 872-6562

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.

New Offspring Spouse Exam 2 - CSJ
Res.v1

DRAFT

RESEARCH CONSENT FORM
CTADD Exam 2 - Offsite

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

Background
The Computed Tomography (CT) Study is an observational research study designed to identify the relationship between calcium deposits in the coronary arteries and other health conditions. You are being asked to participate in this study because you are a woman over the age of 40 or a male over the age of 35 and are enrolled in the Framingham Heart Study.

Purpose
The purpose of this research study is to investigate the role of calcium deposits in the aorta and coronary arteries in the development of 1) 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; and 2) to examine the role of inherited factors (genes) in calcification of the aorta and coronary arteries.

What Happens In This Research Study
You will be one of approximately 2900 subjects to be asked to participate in this study.

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

Your research examination will take place at the PARC Center, located at 40 Second Avenue, Suite 120 (CT/MRI Services) in Waltham, MA at Massachusetts General

Hospital West. The examination will take approximately 30 minutes and will include the following Computed Tomography scan taking about 20 minutes:

1) The CT Scan
A Computed Tomography (CT) scan will be performed for research purposes at Mass General Hospital West (MGHW) Medical Center in Waltham, MA. This is a new type of x-ray done to measure the amount of calcium in the arteries of your heart and abdomen.

For this scan, you will lie on a table with just your torso (not your head) inside the doughnut shaped CT scanner. You will be asked to remain still and hold your breath for about 20-30 seconds several times during the scan.

Two scans of your coronary arteries and one scan of your abdominal aorta will be performed.

2) Pregnancy Test (for some women only)
Most women will be asked to provide a urine sample for a pregnancy test within 24 hours before the CT scan. Women who are not pregnant after undergoing the pregnancy test will proceed with the CT scan. If the pregnancy test is positive you will be referred to your physician for follow up and the scan will not be performed.

This CT scan will not be done on women who are pregnant or who have been breast feeding for less than six months.

3) Results
When the CT scan is read the amount of calcium in your arteries is given a score. At present, it is the opinion of experts that the results scores of the amount of coronary calcium detected by CT scanner are not usually used to make clinical decisions. Therefore, the results of the calcium tests or of genetic research that results from the CT scanning tests will not routinely be reported to your physician. However, markedly abnormal levels of calcium deposits in your arteries will be reported to your physician.

A complete clinical evaluation of the CT scan image for abnormalities in the chest and abdomen will not be performed for clinically important findings.

Incidental Findings: In the event that the research evaluation of the scan does uncover medical problems that require medical diagnosis for treatment, you will be told and the information will be provided to the physician or clinic that you choose.

This CT scan is being conducted for research purposes. The CT scan is being done only to measure calcium in the heart and major arteries. Because a complete clinical evaluation of the CT scan images for all possible abnormalities in the chest and abdomen will not be performed, some clinically important findings may not be discovered.

You will be asked to sign an additional medical release form giving permission to MGHW to release your CT information to the Framingham Heart Study Investigators.

Any questions you have regarding your rights as a research subject may 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
The CT scan of the heart and abdomen involves low doses of radiation. The total amount of radiation per scan is 1 msv or less than 8% of the yearly radiation exposure limit allowed for a radiation worker. Another way of understanding this is that the total amount of radiation is approximately equivalent to the radiation exposure from 2 mammograms.

The risk from this amount of radiation (X-rays) is generally recognized to be safe by the Food and Drug Administration (FDA) for such studies.

We do not expect an unusual risk or injury to occur as a result of your participation. 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 medical conditions involving the heart, 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 the scan. If the research evaluation of the CT scan examination uncovers markedly abnormal levels of calcium deposits in your arteries or 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. However, if necessary, we will provide transportation from FHS to and from the center at no cost.

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 numbers will be provided only to qualified investigators.

You will not be informed of the results of the research including the genetic research that may arise from the CT scan, although genetic tests may be developed as a result of the combined analysis of data in the Framingham Heart Study.

When study results based on your information are published, your name and any other potentially identifying information (i.e. code numbers) will not be revealed. You will be kept informed through periodic publications from the Framingham Heart Study of any new information of findings about CT testing or genetic findings related to CT testing for cardiovascular disease or other health conditions, which may be of importance to you and/or your family.

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 that you agree with:

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

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 (508) 872-6562

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.

CTADD Exam 2 - Offsite

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.

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

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 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 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.

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 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).
The Blood Draw: Minimal bruising, pain, or bleeding 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
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 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.

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.

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.

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.

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 (508) 872-6562

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.

Offspring Exam 8
Res.v6

RESEARCH CONSENT FORM
Offspring Exam 8 - Offsite

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.

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 73 Mount Wayte Avenue in Framingham, MA or other facility/residence.

The Framingham Heart Study Examination takes about 2 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
You will be asked to participate in standard measurements routinely done in your physician's office such as height, weight and blood pressure. The electrocardiogram measures the rate and regularity of your heartbeats

You will be asked questions to assess your ability to perform activities of daily living, general daily functioning, and measures or memory and mood.

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 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 urine specimens
Genetic Studies: You will not be asked to provide a blood sample at this visit, although we will use previously frozen blood samples for testing of potential risk factors for the diseases and health conditions under investigation. Some participants may be asked to provide a small sample of blood for the creation of a cell line. A cell line is a frozen sample of specifically 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. 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 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.

The previous frozen blood samples will also be tested for genetic studies.

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) 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.

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:

Observed Performance: this test involves a very low level of risk. The primary risk is injury from falling.

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.

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.

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) |___| 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 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).

3) |___| 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.

4) |___| 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.

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

6) |___| 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.)

7) |___| 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.

8) |___| 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 (508) 872-6562

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.

Offspring Exam 8 - Offsite
Res.v7

RESEARCH CONSENT FORM
Blood Draw Consent for Cell Line Creation

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

Background
A cell line is a frozen sample of specially processed white cells from your blood that allows the Framingham Heart Study to grow more white cells and get more DNA from them in future as needed for research projects.

Purpose
A cell line will be created from a blood sample you provide in order to study the cause and prevention of cardiovascular disease and other health conditions, including the possibility of how genetic factors influence health status.

What Happens In This Research Study
You will be one of approximately 150 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 blood draw will take place at the Framingham Heart Study facility located at 73 Mount Wayte Avenue in Framingham, MA or the place where you reside.

A laboratory technician will draw a sample of your blood (16 cc or about 1 tablespoon) for the preparation of DNA (genetic material) and for the creation of a living tissue sample (cell line).

Risks and Discomforts
Minimal bruising, pain, or bleeding 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.

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 cause and prevention of cardiovascular disease and other health conditions, including the possibility of how genetic factors influence health status.

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. 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.

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. Cell lines will be stored at a central site (repository). 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.

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.

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 major 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.

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.

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.

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.

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

1) |___| YES |___| NO I agree to allow a cell line to be made from 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 obtain more DNA from them as needed for future research projects).

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 (508) 872-6562.

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 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.
