OMB Control Number: 0925-0216 Expiration Date: 10/2016

RESEARCH CONSENT FORM

Blood Draw Consent for Cell Line Creation

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 1080 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 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 sample of white blood cells (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.

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Subject Costs and Payments

You will not be charged for the examination. If the examination finds any medical problems requiring 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

Information obtained during this study will be treated as strictly confidential. A code number will be assigned to you and to your personally identifying information. Cell lines will be stored at a central site. Files linking names to samples will be kept locked and accessible only to the Framingham Heart Study (FHS) data managers. The coded samples will be stored securely and kept until no longer of scientific value. The risk in providing this sample is minimal.

Data and DNA will be distributed to the FHS 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 personally 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 identifying information will not be revealed. You will be informed through periodic publications from the FHS of some findings about genetics, cardiovascular disease or other health conditions generated from the DNA analyses.

BUMC/BMC Institutional Review Board
IRB NUMBER: H-32132
IRB APPROVAL DATE: 01/06/2015

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To help us further protect your privacy, the investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes. You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note however, that if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy. Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

You may choose to withdraw your blood samples and your samples would be destroyed after the request is received. 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 FHS 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 FHS is documented in the Federal Register: September 26, 2002 (Vol. 67, No. 1879) pages 60776-60780.

Please check the appropriate box below:

1) |___| YES |___| NO (Office Code 1)

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.

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If at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled.

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

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury while participating in this research, contact PHILIP A. WOLF, MD, or DANIEL LEVY, MD, 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.

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Protection of Subject Health Information

N/A

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

_____

Subject (Signature and Printed Name) Date

_____

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

_____

Person Obtaining Consent (Signature and Printed Name) Date

Framingham Heart Study
Group 3 Exam 3
RESEARCH CONSENT FORM

Welcome Back to the Framingham Heart Study

Together we are helping to fight heart disease and other major diseases and health conditions through research.

Why is the research study being done?

The Framingham Heart Study is a long term research study. The purpose of the study is:

(1) To help understand how heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other major diseases and health conditions develop; and
(2) To examine DNA and its relationship to the risks of developing these diseases and other health conditions.

The research examination that will be conducted as part of this study is not clinical care. The tests are for research purposes only. We do not provide medical services. This research examination does not take the place of medical care by your own health care provider.

About your consent

Please read this research consent form carefully. It tells you important information about the research study. Taking part in a research study is voluntary. The decision whether or not to take part in all or any part of the research exam is entirely up to you. If you choose to take part, you can decide to stop at any time. Your decision will be honored and respected. There will be no penalty to you if you decide to stop or not to take part.

If I have questions or concerns about this research study, whom can I call?

If you have any questions about the research or about this form, please ask us. You can call us with your questions or concerns. You can ask questions as often as you want.

You can call a study staff member directly at (508) 872-6562, or you can send an email to FHS@bu.edu.

The Framingham Heart Study is led by investigators from Boston University and the National, Heart, Lung, and Blood Institute at the National Institutes of Health. Dr. Vasan S Ramachandran and Dr. Daniel Levy are in charge of the research study. You can contact Dr. Ramachandran at (617) 638-8090 Monday to Friday between 9am and 5pm or by email at vasan@bu.edu and Dr. Levy at (508) 935-3400 Monday to Friday between 9am and 5pm or by email at levyd@nih.gov.

If you want to speak to someone not directly involved in the research study, please contact the Boston University Medical Campus (BUMC) Institutional Review Board at (617) 638-7207.

Together we are helping to fight heart disease and other major diseases and health conditions through research.

What will happen in this research exam?

You will need to fast for 12 hours before you come to the study appointment for the blood draw. You can take your usual morning medication and drink water on the morning of your visit.

Your research examination will take place at the FHS Research Center at 73 Mount Wayte Avenue, Framingham, MA, or in your home or other residence. The onsite research exam will take around 4 hours to complete.

As before, we will

- draw a sample of blood for genetic and laboratory tests to better understand risk factors for heart disease and other diseases under investigation (for example, the amount and function of different types of cholesterol in your blood). The total blood draw will be around 120 mL, which is about 8 tablespoons. The blood draw will occur in two stages. The first blood draw soon after your arrival and the second blood draw after the Cardiopulmonary Fitness Evaluation.
- collect a urine sample
- measure your height and weight
- complete an electrocardiogram (ECG)
- record your blood pressure
- update your medical history information
- complete a test of vascular function that tests blood vessel (artery) stiffness by recording the blood pressure waveform
- ask you to sign a form to allow FHS to obtain copies of medical records, including Medicare records. The release form is valid to obtain these records unless canceled by you.
- contact you later by mail, email, or by phone to obtain additional information or to invite you to participate in further FHS related studies. You may also be invited to return for another examination in the future.

Surveys

We will also be asking you to complete questionnaires such as physical function, diet, exercise, memory and mood, and your lifestyle habits, including whether you smoke or use alcohol. Some of the questionnaires you will have seen before and others will be new to you.

Some of your responses will be recorded using a digital audio recorder. Recordings will be analyzed in conjunction with other study information. We will also use recordings to make sure that your responses are accurately documented.

There are some new research activities.

1. Cardiopulmonary Fitness Evaluation: The Cardiopulmonary Fitness Evaluation is designed to find out the efficiency of your heart, lungs, and circulation of blood. We will ask you to exercise on a stationary cycle while you are attached to machines that will record your breathing and heart function. We will ask you to pedal the cycle for as long as you are able. While you are pedaling you will breathe into a tube that will collect and measure the air you breathe in and out. Your heart rate and blood pressure will be watched throughout this activity. We will monitor your heart rate

using an electrocardiogram (ECG) by placing small stick-on pads to your skin. This test will take about 30 minutes in total, with about 10-15 minutes spent actually exercising. At the end of this test, a blood sample of around 25 mL, or 2 tablespoons, will be drawn.

What risks can I expect? As with any moderate exercise you will become tired and short of breath; this is normal. It is likely that your heart rate and blood pressure will increase. In rare instances, abnormal changes may occur such as fainting, irregular heart beat and low blood pressure. In very rare instances heart attack may occur as in any other strenuous activity. Every effort will be made to minimize any possible problem by constant surveillance during testing as well as the ability to stop the tests at any time. Equipment and trained personnel are available to deal with unusual situations, should they arise.

Minimal bruising, pain, bleeding, or in rare circumstances, infection may occur, as a result of the blood draw. Also, although rare, some people feel lightheaded or faint when their blood is drawn.

2. Bone Study: High Resolution-Peripheral Quantitative Computed Tomography bone scan of the forearm and lower leg: While seated, we will place your forearm on a support and then place it inside the machine to take the scan. When we have completed the scan of your arm, we will do the same with your lower leg. It is important that you remain as still as possible for this scan.
Dual-energy x-ray absorptiometry scan of the hip and the whole body: This scan involves lying on a padded table and having the machine pass over and scan your hip and your entire body.

   What risks can I expect? Having bone density tests involve the use of X-rays, which are a form of radiation. However, the radiation that you will be exposed to as part of this study is so small that there is no significant risk to your health.

   Due to potential risk to the fetus, pregnant women, as determined by self-report or by a positive pregnancy test, will be excluded from this test.

3. Desktop AGE Reader (Skin Test): This test measures the amount of a special type of collagen in the skin of your forearm that can be affected by levels of blood sugar. The amount of the special type of collagen in the skin is related to the amount in the bone. We will clean your arm with a wet wipe. You will then place your bare forearm on the reader and it will shine a light on your skin to perform the measurement.

   What risks can I expect? There are no known risks associated with the skin reader.

4. Fibroscan: The fibroscan is a test to measure the presence of fat or scarring in the liver. A painless pulse is generated on your skin that travels to the liver and measures how stiff your liver is.

What risks can I expect? There may be minor discomfort from the application of lubricating jelly and pressure on the skin from the fibroscan probe. However, there are no known risks associated with the fibroscan.

There are some conditions that may interfere with the ability of the device to obtain valid measures. They include being pregnant, having fluid in the abdominal cavity (ascites), and having implanted medical devices, such as a heart pacemaker. We will ask, but please let us know if you have any of these conditions and we will not complete the fibroscan.

5. Additional Medical Record Release for Medicare Using Social Security Numbers: You will be asked if investigators and their research collaborators at other institutions, including Duke University, may link your Social Security Number to the Center for Medicare & Medicaid Services data to obtain Medicare information. Social Security Numbers will not be released to outside institutions for purposes not related to the study except with consent or as required by law.

   What risks can I expect? We do our best to protect your study information (see below). However there is still a risk of loss of confidentiality.

Take home tests:

6. Electronic FHS (eFHS) Study: If you live in the US, have an email account with access to a daily Internet connection or have an iPhone, we will invite you to take part in the eFHS study. Taking part requires that you download apps and use wireless devices. The apps will require you to complete surveys regarding lifestyle and health, and the devices will measure heart rate, blood pressure, weight, and physical activity.

   What risks can I expect? There are no known risks to taking part in this study.

7. Stool Sample Collection: We will ask you if you would like to use a kit to collect a stool sample at home and then to send the sample by mail to a laboratory. The purpose of this study is to better understand the causes of cardiovascular disease and diabetes, by studying what bacteria are present in your gut, and what biological functions they are performing. The take home kit contains instructions and supplies for the stool collection. The kit also contains a sheet with a few questions about how you have been feeling recently, the foods you have been recently eating and the appearance of your stool.

   What risks can I expect? The stool sample collection is inconvenient and might make you feel uncomfortable. You may also be uncomfortable answering some of the questions we ask you in the questionnaire that goes with your stool collection kit. You may choose to not answer any questions that you do not feel comfortable

answering. Your answers will be kept confidential and will not be associated with your name or personal identifying information.

8. Accelerometer: You will be asked to wear a physical activity monitor on a belt for a week and to return it to FHS. It measures how active you are throughout the day.

What risks can I expect? There are no known risks to taking part in this study.

General Risks: The research exam is time consuming and repetitive. Other discomforts include headaches, feeling hungry due to fasting, fatigue and chill during the visit. We do not expect any risk of injury as a result of your participation in the study. However, first aid will be available.

Unknown Risks: There may also be some risks that we are unable to determine at this time.

Genetic Studies

We plan to do genetic research on the DNA from your biological samples. The biological samples include blood cells, tissue cells, stool samples, etc. DNA is the material that makes up your genes. Genes are passed from parent to child. All living things are made of cells. Genes are the part of cells that contain the instructions which tell our bodies how to grow and work and determine physical characteristics such as hair and eye color.

Also, if you agree, we will process white blood cells from a sample of your blood to become stem cells in the laboratory. The resulting cells are known as Induced Pluripotent Stem Cells (iPS cells), and they will be used in the laboratory to act like cells from other organs, such as liver cells, fat cells, heart cells, lung cells, vascular cells, gut cells, nerve cells, different types of blood cells, and many other engineered or naturally occurring cell types. These cells and the cell products that can be obtained from them such as RNA, proteins, and metabolites may be studied in laboratories to learn more about the causes of health and diseases of these organs.

Your cells will be stored indefinitely in a stem cell repository at Boston University. Your cells may also be stored in a central repository or bank.

If you agree, your stored tissues, cells and any resulting iPS cell lines or their derivatives could be used in future related and unrelated research studies including:

- Injecting or transplanting the stem cells or their derivatives into animals for research purposes. Your samples may be used in research that involves genetic manipulation but they will not be used to clone or to otherwise create an entire human being.
- Testing for genetic and DNA composition. Genes may be analyzed and/or manipulated to study normal function or development, and some of the DNA in the stem cells or their derivatives may be altered.
- Other uses involving research or development of commercial products for the

diagnosis, prevention, or treatment of various diseases.

- Samples (blood cells, the iPS cells, or their derivatives) obtained from you in this study may be used in the development of one or more diagnostic or therapeutic products which could be patented and licensed by those involved in the research or development of such products. There are no plans to provide financial compensation to you should this occur.

How will I learn the results of this study?

The main way results of research from this study are reported is in scientific publications and presentations at scientific meetings. Summary findings are also sometimes described in our newsletters.

We will also report some routine research test measurements to you and/or your health care provider at the time of the exam or after your visit. These may include, for example, blood pressure and cholesterol.

In some cases, if we determine it to be appropriate, we may report to you and/or your health care provider research findings as they relate to you, if you give your permission. This information, if it is reported, might be reported long after your visit for a number of reasons. As an example, it might take years of work to analyze information and arrive at research findings, possibly using newly developed scientific methods.

Our genetic research might generate findings that could be relevant to you and possibly your family members, such as information about a particular genetic variant that might put you at risk of a serious health condition. At this time, we believe that most of the genetic research findings do not have medical importance to individuals, but the field of genetics is changing rapidly.

We currently do not have specific plans to contact you or your health care provider about genetic or non-genetic research findings other than some routine research test measurements. In general, we cannot commit to providing any other research findings to you. In determining whether we share additional research information with you, we will take into account a number of considerations on a case-by-case basis. These might include whether the findings were based on tests that are clinically acceptable, accurate and reliable, whether the findings reveal a significant risk of a serious health condition, whether there is at the relevant time a recognized treatment or prevention intervention or other available actions that have the potential to change the clinical course of the health condition, whether reporting or not reporting the results is likely to increase the risk of harm to you, and other relevant factors that we might not be able to predict at this time.

Research test measurements and findings are not the same as clinical test results. As such, our research examination is not necessarily performed by individuals with clinical training and qualifications, and many parts of the examination do not meet the standards for certified clinical testing. For these reasons, our research tests should not be relied on to make any diagnosis,

treatment, or health planning decisions. We do not provide health care or give medical advice or genetic testing or provide counseling. If you or your health care provider decides that follow-up tests or treatments are necessary, then you (or a third party such as a health insurance carrier or Medicare) will be responsible for the cost.

How are my samples and information shared with other researchers?

Samples and information will be kept indefinitely. If you agree, your data and donated blood, blood cells, resulting iPS cells or their derivatives, urine, and any other specimens may be shared with other researchers. These include other academic, non-profit, and for-profit entities, including but not limited to hospitals, universities, cell/tissue storage banks and repositories, databanks and data repositories, and businesses, whether for related or unrelated research studies. They will not be labeled with your name or other direct personal identifiers, only a code.

Coded audio recording information will be analyzed by qualifying collaborators inside and outside of BUMC. Your name and other direct personal identifiers will not be shared with these entities.

You have the right to refuse to allow your data and samples to be used or shared for further research. Please check the appropriate box in the selection below.

If you give your permission to allow your data and biological samples to be used or shared for further research, you may withdraw your permission at any time by contacting the FHS investigators. However, if your data or samples have already been released to other researchers, we will not be able to instruct the other researchers to stop using them, to destroy them or products made from them. Your data and samples will not include your name or other direct identifiers.

What risks can I expect?

Participating in genetic research could have a negative impact on you, your family, and your loved ones. The genetic studies might result in research findings that relate to your risk of a serious health condition or other genetic information that we might consider to be appropriate to report to you and your health care provider, if you wish us to report them (see below). This could present you with some difficult decisions regarding the available information and the disease risks you and your family members might face. Knowledge of genetic research findings can provoke anxiety and influence decisions regarding marriage, family planning, and other matters.

How is my information protected?

We take steps to make sure that the personal information we collect about you is kept private and secure. We *label* your samples and information with a code, and we keep the key to the code in a password protected database. Only approved staff is given the password. We use other safeguards at our facilities and for our information technology and systems to protect the privacy and security of your information.
We do not sell, rent, or lease your contact information.

If information from this study is published or presented at scientific meetings, and when your samples and information are shared with other researchers and deposited in data and specimen banks and repositories, your name and other direct personal identifiers will not be used.

However, we cannot guarantee total privacy. We may give access to your information in order to do the study and to make sure we do the study according to certain standards set by ethics, law, and quality groups. Information may be made available to researchers that are part of this study, the Institutional Review Board that oversees this research, research and non-research staff and organizations who need the information to do their jobs for the conduct and oversight of the study, people or groups that we hire to do work for us (such as data or biosample storage companies, insurers, and lawyers), and Federal and state agencies as required by law or if they are involved in the research or its oversight. In most cases, any information that is given out to others is identified by code and not with your name or other direct personal identifiers. Once information is given to outside parties, we cannot promise that it will be kept private. Please be aware that your personal information may be given out if required by law (e.g., to prevent possible injury to yourself or others).

To help us further protect your privacy, the investigators have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer or employer learns of your participation, and obtains your consent to receive research information, then FHS is not allowed to use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy. Finally, you should understand that the Certificate of Confidentiality does not prevent the investigators from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

Patenting Discoveries

Research from this study may, one day, result in new tests to diagnose or predict diseases. It may also lead to the development of new ways to prevent or treat diseases. As is true of all federally-funded research, researchers and their employers are permitted by Federal law to patent discoveries from which they may gain financially. You and your heirs will not benefit financially.

What are the possible benefits from being in this research study?

You will not be paid for your participation in this study, and you will not receive any personal health benefits as a result of your participation in this study. We hope that this study will help us better understand what causes heart disease and other diseases and conditions and how to better prevent and treat them.

What are the costs of taking part in the study?

Costs that you may incur on the day of your participation include, but are not limited to, loss of work and transportation costs (gas, tolls, etc.).

No special arrangement will be made by the Framingham Heart Study for compensation or payment solely because of your participation in this study. If you think you have been injured by being in this study, please let the investigators know right away. Boston University and the sponsors do not offer a program to provide compensation for the cost of care for research related injury or other expenses such as lost wages, disability, pain, or discomfort. You will be sent a bill for the medical care you receive for research injury if your medical insurance does not pay for your medical care. This does not waive any of your legal rights.

How long will I be in the study?

FHS is a long term study.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

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.

Please read the following statements and check the appropriate box below:

1) I agree to participate in the FHS examination, including the collection of data, blood, urine samples, and various research tests and measurements. I agree to the use of all data, samples, and research materials for studies of the factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other diseases and health conditions.

   |___| YES |___| NO (Office Code 0)

2) I agree to allow Induced Pluripotent Stem Cells (iPS cells) to be made from my blood and altered so that they function like cells from other organs.

   |___| YES |___| NO (Office Code 13)

3) I agree to allow my data, blood, DNA and other genetic material, iPS cells and their derivatives, urine samples, and any other specimens to be used in genetic research, of factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other diseases and health conditions.

   |___| YES |___| NO (Office Code 3)

4) I agree to allow researchers from commercial companies to have access to my data, blood, DNA and other genetic material, iPS cells and their derivatives, urine samples, and any other specimens for research. I understand that my data and specimens will be shared without my name or direct personal identifiers.

   |___| YES |___| NO (Office Code 4)

5) I agree to allow the FHS to release the findings of non-genetic research tests and examinations to me and/or my physician, clinic, hospital, or other health care provider.

   |___| YES |___| NO (Office Code 30)

6) I agree to allow the FHS to provide me, and with my permission, my physician, clinic, hospital, or other health care provider information relating to genetic research findings as they may relate to me.

   |___| YES |___| NO (Office Code 31)

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

Participant's Signature	**Printed Name**	**Date**

Legally Authorized Representative (LAR)'s Signature	**Printed Name**	**Date**

Person Obtaining Consent Signature	**Printed Name**	**Date**

RESEARCH CONSENT FORM

Blood Draw Consent for Cell Line Creation

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 1080 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 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 sample of white blood cells (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.

RESEARCH CONSENT FORM

Blood Draw Consent for Cell Line Creation

THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

Subject Costs and Payments

You will not be charged for the examination. If the examination finds any medical problems requiring 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

Information obtained during this study will be treated as strictly confidential. A code number will be assigned to you and to your personally identifying information. Cell lines will be stored at a central site. Files linking names to samples will be kept locked and accessible only to the Framingham Heart Study (FHS) data managers. The coded samples will be stored securely and kept until no longer of scientific value. The risk in providing this sample is minimal.

Data and DNA will be distributed to the FHS 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 personally 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 identifying information will not be revealed. You will be informed through periodic publications from the FHS of some findings about genetics, cardiovascular disease or other health conditions generated from the DNA analyses.

BUMC/BMC Institutional Review Board
IRB NUMBER: H-32132
IRB APPROVAL DATE: 01/06/2015

RESEARCH CONSENT FORM

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THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

To help us further protect your privacy, the investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes. You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note however, that if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy. Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

You may choose to withdraw your blood samples and your samples would be destroyed after the request is received. 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 FHS 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 FHS is documented in the Federal Register: September 26, 2002 (Vol. 67, No. 1879) pages 60776-60780.

Please check the appropriate box below:

1) |___| YES |___| NO (Office Code 1)

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.

RESEARCH CONSENT FORM

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If at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled.

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

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury while participating in this research, contact PHILIP A. WOLF, MD, or DANIEL LEVY, MD, 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.

RESEARCH CONSENT FORM

Blood Draw Consent for Cell Line Creation

THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

Protection of Subject Health Information

N/A

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

_____

Subject (Signature and Printed Name) Date

_____

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

_____

Person Obtaining Consent (Signature and Printed Name) Date

RESEARCH CONSENT FORM

Gen3, NOS, Omni 2 Exam 3

THE FRAMINGHAM HEART STUDY

Background

You are participating in the continuation of the Framingham Heart Study (FHS). The Framingham Heart Study is a research study. Your third FHS research examination will be similar to the previous two in many ways. Exam components, both old and new, are described below.

Purpose

The purpose of this research is 1) to better understand the development of heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other major diseases and health conditions; and 2) to examine DNA and its relationship to the risks of developing these diseases and other health conditions.

THE FHS RESEARCH EXAMINATION IS FOR RESEARCH PURPOSES. WE ARE NOT A MEDICAL FACILITY AND WE DO NOT PROVIDE MEDICAL SERVICES. YOUR RESEACH EXAMINATION DOES NOT TAKE THE PLACE OF A ROUTINE MEDICAL CHECK UP BY YOUR PHYSICIAN.

Right to Refuse or Withdraw

Taking part in this study is voluntary. You have the right to refuse to take part in all or any part of this study. There will be no penalty to you for not taking part. 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 you being able to get health care at Boston Medical Center 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.

What Happens In This Research Study

Your research examination will take place at the FHS at 73 Mt. Wayte Avenue in Framingham. Some research will be completed at Boston University Medical Center.

Ongoing Exam components for which you have previously given informed consent:

1) Medical History Interview.

2) Physical Examination including ECG, blood pressure, height, weight, waist circumference

3) Collection of blood and urine specimens to test for many risk factors for the diseases and health conditions under investigation.

4) Genetic Studies: You will be asked if a sample of the blood you donate may be used for additional genetic studies.

5) Questionnaires about memory, mood and physical function; diet and exercise

6) Medical Records: You will be asked to sign a form to allow FHS to obtain copies of hospital and Medicare (CMS) and medical records. The release form is valid to obtain these records unless canceled by you. You will be asked for your social security number for the purpose of locating you in the future. You may choose to decline this request. You will also be asked if investigators and their research collaborators at other institutions, in this case Duke University, may link your Social Security Number to CMS data to obtain Medicare information. Social Security Numbers will not be released to outside institutions.

7) Results of some FHS research measurements may be sent to you and/or to your physician. However, it may be months or years later, after being reviewed as part of special research projects.

8) Follow Up: You may be contacted later by mail or by phone to obtain additional health information or to be invited to participate in further FHS health-related studies. You may be invited to return for another examination in the future.

In the event that you may have a stroke, you would be examined during your hospitalization (if applicable) and at 3, 6, 12, and 24 months. The examination would include a neurological-evaluation and an assessment of your ability to perform daily activities.

You may also be invited to take part in some ancillary studies.
If you live in the US, have an email account with access to a daily internet connection or have an iOS or Android based smartphone, we will invite you to take part in the electronic FHS study. Taking part requires that you download apps and use wireless devices. The apps will require you to complete surveys regarding lifestyle and health and the devices will measure heart rate, blood pressure, weight, and physical activity.

Details of other ancillary studies will follow.

Risks and Discomforts

Risk or injury, as a result of participation, is not expected. In the unlikely event that during the examination you require medical care, first aid will be available.

The Blood Draw: Minimal bruising, pain, bleeding, or in rare circumstances, an infection may occur.

Other discomforts include headaches, feeling hungry due to fasting, fatigue and chill during the visit. The exam is time consuming and repetitive. A urine collection is inconvenient.

Safeguards are in place to protect the security of your study information. FHS ID numbers are used on most data files instead of names. Firewalls and password protection are in place on the computer systems. Staff is trained in safe computer practices. However there is still a minimal risk of a breach in confidentiality.

There is potential risk in genetic testing for uncovering and conveying unwanted information regarding parentage or specific risk of disease. Also, sometimes, knowledge of DNA test results can provoke anxiety and influence decisions regarding marriage and family planning.

Both Massachusetts state laws and a new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally make it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. These laws generally will protect you in the following ways:

1. *Health insurance companies and group health plans may not request your genetic information that we get from this research.*
2. *Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.*
3. *Employers with 6 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.*

All health insurance companies and group health plans must follow the GINA law by May 21, 2010. All employers with 15 or more employees must follow the GINA law as of November 21, 2009. Massachusetts law currently applies to all employers of 6 or more employees.

Be aware that neither Massachusetts law nor the new Federal law protects you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Thus, life insurance, disability insurance and long-term care insurance companies may legally ask whether you have had genetic testing and deny coverage for refusal to answer this question.

Potential Benefits

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand the causes and prevention of cardiovascular disease and other medical conditions, including the potential of genetic factors.

Alternatives

Your alternative is to not participate in the study.

Subject Costs and Payments

You will not be charged or paid for any part of the examination. If the examination finds medical problems that require tests or treatments, information will be provided to you and to the physician or clinic that you have named to receive your test results. If your physician decides that follow up tests or treatments are necessary, then you (or a third party such as health insurance or Medicare) will be responsible for the cost. No special arrangement will be made by the Framingham Heart Study for compensation or payment solely because of your participation in this study. This does not waive any of your legal rights. Costs that you may incur on 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.

Patenting Discoveries

Research from this study may, one day, result in new tests to diagnose or predict diseases. It may also lead to the development of new medicines to prevent or cure diseases. As is true of all federally-funded research, researchers and their employers are permitted by Federal law to patent discoveries from which they may gain financially. It was the judgment of the U.S. Congress that permitting such patents would greatly increase the likelihood that a public health benefit would be realized from federally funded research.

Confidentiality

Information obtained about you will be treated as confidential. A code number will be assigned to your data and specimens. The codes will only be provided to qualified investigators but your name and other personally identifying information will not be provided. Your samples will be kept until they are not of scientific value. You will not be routinely informed of results of research performed upon your genetic samples, although with your permission you may be informed of some findings about genetics, cardiovascular disease or other health conditions generated from DNA analyses, directly to you or through publication in newsletters.

When study results are published, your name and other identifying information will not be revealed. Information from this study and from your medical record may be reviewed and photocopied by 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.

To help us further protect your privacy, the investigators have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer or employer learns of your participation, and obtains your consent to receive research information, then FHS is not allowed to use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy. Finally, you should understand that the Certificate of Confidentiality does not prevent the investigators from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

Please check the appropriate box above each of the following statements:

1) |___| YES |___| NO (Office Code 0)

I agree to participate in the FHS clinic examination, the collections of blood and urine, and studies of the factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other major diseases and health conditions.

2|___| YES |___|NO (Office Code 3)

I agree to allow my data, blood and urine samples to be used in future genetic studies of factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other diseases and health conditions.

3) |___| YES |___| NO (Office Code 12)

I agree to allow my data, blood and urine and DNA samples to be used in future genetic studies of reproductive conditions, and mental health conditions such as alcohol use and depressive symptoms.

4) |___| YES |___| NO (Office Code 4)

I agree to allow researchers from commercial companies to have access to my blood and urine samples, DNA, other genetic material, and data in the future which may be used to develop new lab tests or treatments that could benefit many people. (You or your heirs will not benefit financially from this, nor will your DNA be sold to anyone.)

5) |___| YES |___| NO (Office Code 30)
I agree to allow the FHS to release the findings of non-genetic tests and examinations to my physician,clinic, or hospital.

6) |___| YES |___| NO (Office Code 31)
If a genetic condition is identified that may have important health and treatment implications for me, I agree to allow the FHS to notify me, and then with my permission to notify my physician.

Subject's Rights

By consenting to participate in this study you do not waive any of your legal rights. Giving consent means that you have heard or read the information about this study and that you agree to participate. You will be given a copy of this form to keep.

If at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled.

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

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury while participating in this research, contact Vasan S. Ramachandran, MD or Daniel Levy, MD 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 of the study is not at Boston Medical Center, ask the investigator where treatment for injury would be available locally. Boston University Medical Center and the sponsor do not offer a program to provide compensation for the cost of care for research related injury or other expenses such as lost wages, disability, pain, or discomfort. You will be sent a bill for the medical care you receive for research injury if your medical insurance does not pay for your

medical care. You are not giving up any of your legal rights by signing this form.

Protection of Subject Health Information

You have certain rights related to your health information. These include the right to know who will get your health information and why they will get it. If you choose to be in this research study, we will get information about you as explained below.

HEALTH INFORMATION ABOUT YOU THAT MIGHT BE USED OR GIVEN OUT DURING THIS RESEARCH:

Information from your hospital or office health records at BUMC/BMC or elsewhere. This information is reasonably related to the conduct and oversight of the research study. If health information is needed from your doctors or hospitals outside of BUMC/BMC, you will be asked to give permission for these records to be sent to the researcher.

New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

WHY HEALTH INFORMATION ABOUT YOU MIGHT BE USED OR GIVEN OUT TO

OTHERS The reasons we might use or share your health information are:

- To do the research described here

- To make sure we do the research according to certain standard set by ethics, law, and quality groups

PEOPLE AND GROUPS THAT MAY USE OR GIVE OUT YOUR HEALTH INFORMATION

1. PEOPLE OR GROUPS WITHIN BUMC/BMC

- Researchers involved in this research study

- The BUMC Institutional Review Board that oversees this research

2. PEOPLE OR GROUPS OUTSIDE BUMC/BMC

- People or groups that we hire to do certain work for us, such as data storage companies, or laboratories.

- Federal and state agencies if they are required by law or involved in research oversight. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, the Massachusetts Department of Public Health.

- Organizations that make sure hospital standards are met

- The sponsor(s) of the research study, and people or groups it hires to help them do the research

- Other researchers that are part of this research study

- A group that oversees the research information and safety of this study

Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow. We share your health information only when we must. We ask anyone who gets it from us to protect your privacy. However, once the information leaves BUMC, we cannot promise that it will be kept private.

In most cases any health data that is being given out to others is identified by a unique study number and not with your name. So, although in some cases it is possible to link your name to the study data, this is not usually done.

TIME PERIOD FOR USING OR GIVING OUT YOUR HEALTH INFORMATION

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

YOUR PRIVACY RIGHTS

You have the right not to sign this form that allows us to use and give out your health information for research. If you don't sign this form, you can't be in the research. This is because we need to use the health information to do the research.

You have the right to withdraw your permission to use or share your health information in this research study. If you want to withdraw your permission, you must write a letter to the researchers in charge of this research study.

If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality.

If you withdraw your permission, you cannot continue to be in the study.

You have the right to see and get a copy of your health information that is used or shared for research. However, you may only get this after the research is finished. To ask for this information, please contact the person in charge of this research study.

IF RESEARCH RESULTS ARE PUBLISHED OR USED TO TEACH OTHERS

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information will not be used for these purposes without your specific permission.

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

Participant's Signature	**Printed Name**	**Date**
Legally Authorized Representative (LAR)'s Signature	**Printed Name**	**Date**
Person Obtaining Consent Signature	**Printed Name**	**Date**

RESEARCH CONSENT FORM

Offspring Examination 9

THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

Background

You are participating in the continuation of the Framingham Heart Study (FHS), Offspring Cohort. This ninth examination of the FHS Offspring will be similar to previous visits in many ways. There are also some new study activities. Exam components, both old and new, are described below.

Purpose

The purpose of this research is 1) to better understand the development of heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other major diseases and health conditions; and 2) to examine DNA and its relationship to the risks of developing these diseases and other health conditions.

THIS EXAMINATION IS FOR RESEARCH AND DOES NOT TAKE THE PLACE OF A ROUTINE MEDICAL CHECK UP BY YOUR PHYSICIAN

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

What Happens In This Research Study

You will be one of approximately 5124 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 FHS at 73 Mt. Wayte Avenue in Framingham, MA, or may take place in your home or other residence.

New Study Activities:

1) With your permission, white cells (from the blood collected as a regular part of the FHS exam) will be processed so that they function like cells from other organs such as liver cells, fat cells heart cells or nerve cells. The resulting cells are called Induced Pluripotent Stem cells. These cells may be studied in laboratories to learn more about causes of health and disease in such organs. FHS investigators will not alter white cells to behave as reproductive cells.

2) We will ask if we may obtain a sample of cells from the inside of your cheek by gently scraping the inside surface with a single-use plastic utensil. The cells will be used to examine how changes in DNA called DNA methylation are related to lung function and lung diseases and other diseases,

3) You will be asked to wear a physical activity monitor on a belt for a week and to return it to FHS. It measures how active you are throughout the day.

4) You will be asked after your visit to use a kit to collect urine samples for 24 hours and send it by mail to a laboratory. The kit will be mailed to you for a day convenient to you shortly after this exam visit.

RESEARCH CONSENT FORM

Offspring Examination 9

THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

Ongoing Exam components for which you have previously given informed consent: In addition to the new procedures described above, the following procedures will be done at this visit:

1) Medical History Interview.

2) Physical Examination including ECG

3) Collection of blood (up to 117.5 cc or four ounces) and urine specimens to test for many risk factors for the diseases and health conditions under investigation.

4) Genetic Studies: You will be asked if a sample of the blood you donate may be used for additional genetic studies.

5) Vascular Function Testing: Arterial Tonometry is a measure of arterial stiffness. Along with a very limited view of the aorta (the large artery carrying blood flow from the base of the heart), a waveform is obtained by gently placing a flat sensor over arteries on the arm (brachial and radial), the groin (femoral) and the neck (carotid).

6) Pulmonary function testing is performed by breathing into a tube connected to a machine that measures exhaled air volume and flow. Some individuals may be asked to repeat the testing after using an inhaler to improve airflow.

7) Questionnaires about memory, mood and physical function; diet and exercise

8) Blood pressures in your arms and ankles

(In the event that you may have a stroke, you would be examined during your hospitalization (if applicable) and at 3, 6, 12 and 24 months. The examination would include a neurological-evaluation and an assessment of your ability to perform daily activities.)

9) Medical Records: You will be asked to sign a form to allow FHS to obtain copies of hospital and Medicare (CMS) and medical records. The release form is valid to obtain these records unless canceled by you. You will be asked for your social security number for the purpose of locating you in the future. You may choose to decline this request. You will also be asked if investigators and their research collaborators at other institutions, in this case Duke University, may link your Social Security Number to CMS data to obtain Medicare information. Social Security Numbers to will not be released to outside institutions.

10) Results of some FHS research measurements will be sent to you and/or to your physician within six weeks of your FHS visit. However, some other measurements could be made months or years later as part of special research projects. You may receive results of some measurements long after your FHS visit.

RESEARCH CONSENT FORM

Offspring Examination 9

THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

11) Follow Up: You may be contacted later by mail or by phone to obtain additional health information or to be invited to participate in further FHS health-related studies. You may be invited to return for another examination in the future.

Risks and Discomforts

Risk or injury, as a result of participation, is not expected. In the unlikely event that during the examination you require medical care, first aid will be available.

The Blood Draw: Minimal bruising, pain, bleeding, or in rare circumstances, an infection may occur.

The Cheek Swab: There may be minor irritation of brief duration and/or some may experience a minor sensation of gagging.

The Lung Function test involves a low level of risk. You may feel lightheaded or you may faint and risk 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). Pregnant women, as determined by self-report or by a positive pregnancy test, will be excluded from the second part of the pulmonary function test, which includes the albuterol challenge.

Other discomforts include headaches, feeling hungry due to fasting, fatigue and chill during the visit. The exam is time consuming and repetitive. The 24 hour urine collection is inconvenient.

Safeguards are in place to protect the security of your study information. FHS ID numbers are used on most data files instead of names. Firewalls and password protection are in place on the computer systems. Staff is trained in safe computer practices. However there is still a minimal risk of a breach in confidentiality.

There is potential risk in genetic testing for uncovering and conveying unwanted information regarding parentage or specific risk of disease. Also, sometimes, knowledge of DNA test results can provoke anxiety and influence decisions regarding marriage and family planning:

Both Massachusetts state laws and a new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally make it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. These laws generally will protect you in the following ways:

1. *Health insurance companies and group health plans may not request your genetic information that we get from this research.*

2. *Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.*

3. *Employers with 6 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.*

All health insurance companies and group health plans must follow the GINA law by May 21, 2010. All employers with 15 or more employees must follow the GINA law as of November 21, 2009. Massachusetts law currently applies to all employers of 6 or more employees.

Be aware that neither Massachusetts law nor the new Federal law protects you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Thus, life insurance, disability insurance and long-term care insurance companies may legally ask whether you have had genetic testing and deny coverage for refusal to answer this question.

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 causes and prevention of cardiovascular disease and other medical conditions, including the potential of genetic factors.

Alternatives

Your alternative is to not participate in the study.

Subject Costs and Payments

You will not be charged or paid for any part of the examination. If the examination finds medical problems that require tests or treatments, information will be provided to you and to the physician or clinic that you have named to receive your test results. If your physician decides that follow up tests or treatments are necessary, then you (or a third party such as health insurance or Medicare) will be responsible for the cost. No special arrangement will be made by the Framingham Heart Study for compensation or payment solely because of your participation in this study. This does not waive any of your legal rights. Costs that you may incur on 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.

RESEARCH CONSENT FORM

Offspring Examination 9

THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

Patenting Discoveries

Research from this study may, one day, result in new tests to diagnose or predict diseases. It may also lead to the development of new medicines to prevent or cure diseases. As is true of all federally-funded research, researchers and their employers are permitted by Federal law to patent discoveries from which they may gain financially. It was the judgment of the U.S. Congress that permitting such patents would greatly increase the likelihood that a public health benefit would be realized from federally funded research.

CONFIDENTIALITY

Information obtained about you will be treated as confidential. A code number will be assigned to your data and specimens. The codes will only be provided to qualified investigators but your name and other personally identifying information will not be provided. Your samples will be kept until they are not of scientific value. You will not be routinely informed of results of research performed upon your genetic samples, although with your permission you may be informed of some findings about genetics, cardiovascular disease or other health conditions generated from DNA analyses, directly to you or through publication in newsletters.

When study results are published, your name and other identifying information will not be revealed. Information from this study and from your medical record may be reviewed and photocopied by 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.

To help us further protect your privacy, the investigators have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer or employer learns of your participation, and obtains your consent to receive research information, then FHS is not allowed to use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy. Finally, you should understand that the Certificate of Confidentiality does not prevent the investigators from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

RESEARCH CONSENT FORM

Offspring Examination 9

THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

Please check the appropriate box above each of the following statements:

1) |___| YES |___| NO (Office Code 0)

I agree to participate in the FHS clinic examination, the collections of blood, cheek cells and urine, and studies of the factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other major diseases and health conditions.

2|___| YES |___|NO (Office Code 3)

I agree to allow my data, cheek cells, blood and urine samples to be used in future genetic studies of factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other diseases and health conditions.

3) |___| YES |___| NO (Office Code 12)

I agree to allow my data, cheek cells, blood and urine and DNA samples to be used in future genetic studies of reproductive conditions, and mental health conditions such as alcohol use and depressive symptoms.

4 |___| YES |___|NO (Office Code 13)

I agree to provide a blood sample from which Induced Pluripotent Stem Cells can be made and from which a range of cell products such as RNA, proteins and metabolites can be obtained. This means that white cells from my blood may be processed to become stem cells and then altered so that they function like cells from other organs such as liver cells, fat cells, heart cells or nerve cells.

5 |___| YES |___| NO (Office Code 4)

I agree to allow researchers from commercial companies to have access to my blood and urine samples, DNA, other genetic material, and data in the future which may be used to develop new lab tests or treatments that could benefit many people. (You or your heirs will not benefit financially from this, nor will your DNA be sold to anyone.)

6) |___| YES |___| NO (Office Code 30)

I agree to allow the FHS to release the findings of non-genetic tests and examinations to my physician, clinic, or hospital.

7) |___| YES |___| NO (Office Code 31)

If a genetic condition is identified that may have important health and treatment implications for me, I agree to allow the FHS to notify me, and then with my permission to notify my physician.

RESEARCH CONSENT FORM

Offspring Examination 9

THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

Subject's Rights

By consenting to participate in this study you do not waive any of your legal rights. Giving consent means that you have heard or read the information about this study and that you agree to participate. You will be given a copy of this form to keep.

If at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled.

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

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury while participating in this research, contact PHILIP WOLF, MD or DANIEL LEVY, MD 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 of the study is not at Boston Medical Center, ask the investigator where treatment for injury would be available locally. Boston University Medical Center and the sponsor do not offer a program to provide compensation for the cost of care for research related injury or other expenses such as lost wages, disability, pain, or discomfort. You will be sent a bill for the medical care you receive for research injury if your medical insurance does not pay for your medical care. You are not giving up any of your legal rights by signing this form.

Right to Refuse or Withdraw

Taking part in this study is voluntary. You have the right to refuse to take part in this study. If you decide to be in the study and then change your mind, you can withdraw from the research. Your participation is completely up to you. Your decision will not affect you 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.

RESEARCH CONSENT FORM

Offspring Examination 9

THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

Protection of Subject Health Information

You have certain rights related to your health information. These include the right to know who will get your health information and why they will get it. If you choose to be in this research study, we will get information about you as explained below.

HEALTH INFORMATION ABOUT YOU THAT MIGHT BE USED OR GIVEN OUT DURING THIS RESEARCH:

Information from your hospital or office health records at BUMC/BMC or elsewhere. This information is reasonably related to the conduct and oversight of the research study. If health information is needed from your doctors or hospitals outside of BUMC/BMC, you will be asked to give permission for these records to be sent to the researcher.

New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

WHY HEALTH INFORMATION ABOUT YOU MIGHT BE USED OR GIVEN OUT TO OTHERS

The reasons we might use or share your health information are:

- To do the research described here
- To make sure we do the research according to certain standard set by ethics, law, and quality groups

PEOPLE AND GROUPS THAT MAY USE OR GIVE OUT YOUR HEALTH INFORMATION

1. PEOPLE OR GROUPS WITHIN BUMC/BMC

- Researchers involved in this research study
- The BUMC Institutional Review Board that oversees this research

2. PEOPLE OR GROUPS OUTSIDE BUMC/BMC

- People or groups that we hire to do certain work for us, such as data storage companies, or laboratories.
- Federal and state agencies if they are required by law or involved in research oversight. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, the Massachusetts Department of Public Health.
- Organizations that make sure hospital standards are met
- The sponsor(s) of the research study, and people or groups it hires to help them do the research
- Other researchers that are part of this research study
- A group that oversees the research information and safety of this study

RESEARCH CONSENT FORM

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Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow. We share your health information only when we must. We ask anyone who gets it from us to protect your privacy. However, once the information leaves BUMC, we cannot promise that it will be kept private.

In most cases any health data that is being given out to others is identified by a unique study number and not with your name. So, although in some cases it is possible to link your name to the study data, this is not usually done.

TIME PERIOD FOR USING OR GIVING OUT YOUR HEALTH INFORMATION

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

YOUR PRIVACY RIGHTS

You have the right not to sign this form that allows us to use and give out your health information for research. If you don't sign this form, you can't be in the research. This is because we need to use the health information to do the research.

You have the right to withdraw your permission to use or share your health information in this research study. If you want to withdraw your permission, you must write a letter to the researchers in charge of this research study.

If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality.

If you withdraw your permission, you cannot continue to be in the study.

You have the right to see and get a copy of your health information that is used or shared for research. However, you may only get this after the research is finished. To ask for this information, please contact the person in charge of this research study.

IF RESEARCH RESULTS ARE PUBLISHED OR USED TO TEACH OTHERS

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information will not be used for these purposes without your specific permission.

RESEARCH CONSENT FORM

Offspring Examination 9

THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

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

_____	_____	_____
Participant's Signature	**Printed Name**	**Date**
_____	_____	_____
Legally Authorized Representative (LAR)'s Signature	**Printed Name**	**Date**
_____	_____	_____
Person Obtaining Consent Signature	**Printed Name**	**Date**

RESEARCH CONSENT FORM

Omni 1 Exam 4

THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

Background

You are participating in the continuation of the Framingham Heart Study (FHS), Omni Group 1 cohort. This fourth examination of the FHS Omni 1 cohort will be similar to previous visits in many ways. There are also some new study activities. Exam components, both old and new, are described below.

Purpose

The purpose of this research is 1) to better understand the development of heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other major diseases and health conditions; and 2) to examine DNA and its relationship to the risks of developing these diseases and other health conditions.

THIS EXAMINATION IS FOR RESEARCH AND DOES NOT TAKE THE PLACE OF A ROUTINE MEDICAL CHECK UP BY YOUR PHYSICIAN

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

What Happens In This Research Study

You will be one of approximately 520 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 FHS at 73 Mt. Wayte Avenue in Framingham, MA, or may take place in your home or other residence.

New Study Activities:

1) With your permission, white cells (from the blood collected as a regular part of the FHS exam) will be processed so that they function like cells from other organs such as liver cells, fat cells, heart cells or nerve cells. The resulting cells are called Induced Pluripotent Stem cells. These cells may be studied in laboratories to learn more about causes of health and disease in such organs. FHS investigators will not alter white cells to behave as reproductive cells.

2) We will ask if we may obtain a sample of cells from the inside of your cheek by gently scraping the inside surface with a single-use plastic utensil. The cells will be used to examine how changes in DNA called DNA methylation are related to lung function and lung diseases and other diseases,

RESEARCH CONSENT FORM

Omni 1 Exam 4

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3) You will be asked to wear a physical activity monitor on a belt for a week and to return it to FHS. It measures how active you are throughout the day.

4) You will be asked after your visit to use a kit to collect urine samples for 24 hours and send it by mail to a laboratory. The kit will be mailed to you for a day convenient to you shortly after this exam visit.

Ongoing Exam components for which you have previously given informed consent: In addition to the new procedures described above, the following procedures will be done at this visit:

1) Medical History Interview.

2) Physical Examination including ECG

3) Collection of blood (up to 117.5 cc or four ounces) and urine specimens to test for many risk factors for the diseases and health conditions under investigation.

4) Genetic Studies: You will be asked if a sample of the blood you donate may be used for additional genetic studies.

5) Vascular Function Testing: Arterial Tonometry is a measure of arterial stiffness. Along with a very limited view of the aorta (the large artery carrying blood flow from the base of the heart), a waveform is obtained by gently placing a flat sensor over arteries on the arm (brachial and radial), the groin (femoral) and the neck (carotid).

6) Pulmonary function testing is performed by breathing into a tube connected to a machine that measures exhaled air volume and flow. Some individuals may be asked to repeat the testing after using an inhaler to improve airflow.

7) Questionnaires about memory, mood and physical function; diet and exercise

8) Blood pressures in your arms and ankles

(In the event that you may have a stroke, you would be examined during your hospitalization (if applicable) and at 3, 6, 12 and 24 months. The examination would include a neurological-evaluation and an assessment of your ability to perform daily activities.)

9) Medical Records: You will be asked to sign a form to allow FHS to obtain copies of hospital and Medicare (CMS) and medical records. The release form is valid to obtain these records unless canceled by you. You will be asked for your social security number for the purpose of locating you in the future. You may choose to decline this request. You will also be asked if investigators and their research collaborators at other institutions, in this case Duke University, may link your Social Security Number to CMS data to obtain Medicare information. Social Security Numbers to will not be released to outside institutions.

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10) Results of some FHS research measurements will be sent to you and/or to your physician within six weeks of your FHS visit. However, some other measurements could be made months or years later as part of special research projects. You may receive results of some measurements long after your FHS visit.

11) Follow Up: You may be contacted later by mail or by phone to obtain additional health information or to be invited to participate in further FHS health-related studies. You may be invited to return for another examination in the future.

Risks and Discomforts

Risk or injury, as a result of participation, is not expected. In the unlikely event that during the examination you require medical care, first aid will be available.

The Blood Draw: Minimal bruising, pain, bleeding, or in rare circumstances, an infection may occur.

The Cheek Swab: There may be minor irritation of brief duration and/or some may experience a minor sensation of gagging.

The Lung Function test involves a low level of risk. You may feel lightheaded or you may faint and risk 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). Pregnant women, as determined by self-report or by a positive pregnancy test, will be excluded from the second part of the pulmonary function test, which includes the albuterol challenge.

Other discomforts include headaches, feeling hungry due to fasting, fatigue and chill during the visit. The exam is time consuming and repetitive. The 24 hour urine collection is inconvenient.

Safeguards are in place to protect the security of your study information. FHS ID numbers are used on most data files instead of names. Firewalls and password protection are in place on the computer systems. Staff is trained in safe computer practices. However there is still a minimal risk of a breach in confidentiality.

There is potential risk in genetic testing for uncovering and conveying unwanted information regarding parentage or specific risk of disease. Also, sometimes, knowledge of DNA test results can provoke anxiety and influence decisions regarding marriage and family planning:

Both Massachusetts state laws and a new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally make it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. These laws generally will protect you in the following ways:

RESEARCH CONSENT FORM

Omni 1 Exam 4

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1. *Health insurance companies and group health plans may not request your genetic information that we get from this research.*

2. *Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.*

3. *Employers with 6 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.*

All health insurance companies and group health plans must follow the GINA law by May 21, 2010. All employers with 15 or more employees must follow the GINA law as of November 21, 2009. Massachusetts law currently applies to all employers of 6 or more employees.

Be aware that neither Massachusetts law nor the new Federal law protects you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Thus, life insurance, disability insurance and long-term care insurance companies may legally ask whether you have had genetic testing and deny coverage for refusal to answer this question.

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 causes and prevention of cardiovascular disease and other medical conditions, including the potential of genetic factors.

Alternatives

Your alternative is to not participate in the study.

Subject Costs and Payments

You will not be charged or paid for any part of the examination. If the examination finds medical problems that require tests or treatments, information will be provided to you and to the physician or clinic that you have named to receive your test results. If your physician decides that follow up tests or treatments are necessary, then you (or a third party such as health insurance or Medicare) will be responsible for the cost. No special arrangement will be made by the Framingham Heart Study for

compensation or payment solely because of your participation in this study. This does not waive any of your legal rights. Costs that you may incur on 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.

Patenting Discoveries

Research from this study may, one day, result in new tests to diagnose or predict diseases. It may also lead to the development of new medicines to prevent or cure diseases. As is true of all federally-funded research, researchers and their employers are permitted by Federal law to patent discoveries from which they may gain financially. It was the judgment of the U.S. Congress that permitting such patents would greatly increase the likelihood that a public health benefit would be realized from federally funded research.

CONFIDENTIALITY

Information obtained about you will be treated as confidential. A code number will be assigned to your data and specimens. The codes will only be provided to qualified investigators but your name and other personally identifying information will not be provided. Your samples will be kept until they are not of scientific value. You will not be routinely informed of results of research performed upon your genetic samples, although with your permission you may be informed of some findings about genetics, cardiovascular disease or other health conditions generated from DNA analyses, directly to you or through publication in newsletters.

When study results are published, your name and other identifying information will not be revealed. Information from this study and from your medical record may be reviewed and photocopied by 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.

To help us further protect your privacy, the investigators have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer or employer learns of your participation, and obtains your consent to receive research information, then FHS is not allowed to use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy. Finally, you should understand that the Certificate of Confidentiality does not prevent the investigators from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

RESEARCH CONSENT FORM

Omni 1 Exam 4

THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

Please check the appropriate box above each of the following statements:

1) |___| YES |___| NO (Office Code 0)

I agree to participate in the FHS clinic examination, the collections of blood, cheek cells and urine, and studies of the factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other major diseases and health conditions.

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3) |___| YES |___| NO (Office Code 12)

I agree to allow my data, cheek cells, blood and urine and DNA samples to be used in future genetic studies of reproductive conditions, and mental health conditions such as alcohol use and depressive symptoms.

4 |___| YES |___|NO (Office Code 13)

I agree to provide a blood sample from which Induced Pluripotent Stem Cells can be made and from which a range of cell products such as RNA, proteins and metabolites can be obtained. This means that white cells from my blood may be processed to become stem cells and then altered so that they function like cells from other organs such as liver cells, fat cells, heart cells or nerve cells.

5 |___| YES |___| NO (Office Code 4)

I agree to allow researchers from commercial companies to have access to my blood and urine samples, DNA, other genetic material, and data in the future which may be used to develop new lab tests or treatments that could benefit many people. (You or your heirs will not benefit financially from this, nor will your DNA be sold to anyone.)

6) |___| YES |___| NO (Office Code 30)

I agree to allow the FHS to release the findings of non-genetic tests and examinations to my physician, clinic, or hospital.

7) |___| YES |___| NO (Office Code 31)

If a genetic condition is identified that may have important health and treatment implications for me, I agree to allow the FHS to notify me, and then with my permission to notify my physician.

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Omni 1 Exam 4

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If at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled.

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The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury while participating in this research, contact PHILIP WOLF, MD or DANIEL LEVY, MD at (508) 872-6562.

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If you think that you have been injured by being in this study, please let the investigator know right away. If your part in this study takes place at Boston Medical Center, you can get treatment for the injury at Boston Medical Center. If your part of the study is not at Boston Medical Center, ask the investigator where treatment for injury would be available locally. Boston University Medical Center and the sponsor do not offer a program to provide compensation for the cost of care for research related injury or other expenses such as lost wages, disability, pain, or discomfort. You will be sent a bill for the medical care you receive for research injury if your medical insurance does not pay for your medical care. You are not giving up any of your legal rights by signing this form.

Right to Refuse or Withdraw

Taking part in this study is voluntary. You have the right to refuse to take part in this study. If you decide to be in the study and then change your mind, you can withdraw from the research. Your participation is completely up to you. Your decision will not affect you 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.

RESEARCH CONSENT FORM

Omni 1 Exam 4

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Protection of Subject Health Information

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Information from your hospital or office health records at BUMC/BMC or elsewhere. This information is reasonably related to the conduct and oversight of the research study. If health information is needed from your doctors or hospitals outside of BUMC/BMC, you will be asked to give permission for these records to be sent to the researcher.

New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

WHY HEALTH INFORMATION ABOUT YOU MIGHT BE USED OR GIVEN OUT TO OTHERS

The reasons we might use or share your health information are:

- To do the research described here

- To make sure we do the research according to certain standards set by ethics, law, and quality groups

PEOPLE AND GROUPS THAT MAY USE OR GIVE OUT YOUR HEALTH INFORMATION

1. PEOPLE OR GROUPS WITHIN BUMC/BMC

- Researchers involved in this research study

- The BUMC Institutional Review Board that oversees this research

2. PEOPLE OR GROUPS OUTSIDE BUMC/BMC

- People or groups that we hire to do certain work for us, such as data storage companies, or laboratories.

- Federal and state agencies if they are required by law or involved in research oversight. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, the Massachusetts Department of Public Health.

- Organizations that make sure hospital standards are met

- The sponsor(s) of the research study, and people or groups it hires to help them do the research

RESEARCH CONSENT FORM

Omni 1 Exam 4

THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

- Other researchers that are part of this research study

- A group that oversees the research information and safety of this study

Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow. We share your health information only when we must. We ask anyone who gets it from us to protect your privacy. However, once the information leaves BUMC, we cannot promise that it will be kept private.

In most cases any health data that is being given out to others is identified by a unique study number and not with your name. So, although in some cases it is possible to link your name to the study data, this is not usually done.

TIME PERIOD FOR USING OR GIVING OUT YOUR HEALTH INFORMATION

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

YOUR PRIVACY RIGHTS

You have the right not to sign this form that allows us to use and give out your health information for research. If you don't sign this form, you can't be in the research. This is because we need to use the health information to do the research.

You have the right to withdraw your permission to use or share your health information in this research study. If you want to withdraw your permission, you must write a letter to the researchers in charge of this research study.

If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality.

If you withdraw your permission, you cannot continue to be in the study.

You have the right to see and get a copy of your health information that is used or shared for research. However, you may only get this after the research is finished. To ask for this information, please contact the person in charge of this research study.

IF RESEARCH RESULTS ARE PUBLISHED OR USED TO TEACH OTHERS

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information will not be used for these purposes without your specific permission.

RESEARCH CONSENT FORM

Omni 1 Exam 4

THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

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

_____	_____	_____
Participant's Signature	**Printed Name**	**Date**
_____	_____	_____
Legally Authorized Representative (LAR)'s Signature	**Printed Name**	**Date**
_____	_____	_____
Person Obtaining Consent Signature	**Printed Name**	**Date**

FORMA DE CONSENTIMIENTO PARA INVESTIGACION
Omni 1 Examen 4
ESTUDIO DEL CORAZON DE FRAMINGHAM N01-HC-25195 1910G

Antecedentes

Usted está participando en la continuación del estudio para Omni 1 del Estudio del Corazón de Framingham. Este es el cuarto examen y en muchos sentidos será similar a los exámenes previos, pero hay algunas pruebas que son nuevas. Los componentes de este Examen, tanto los anteriores como los nuevos, se describen abajo.

Propósito

El propósito de este estudio es 1) entender mejor el desarrollo de enfermedades del corazón y las arterias, enfermedades del pulmón y la sangre, accidentes cerebro-vasculares, pérdida de memoria, cáncer y otras enfermedades y condiciones de la salud; y 2) examinar el ADN y su relación con los riesgos a desarrollar estas enfermedades y otras condiciones de la salud.

ESTE EXAMEN ES SOLO PARA INVESTIGACION MEDICA Y NO TOMA EL LUGAR DE UN CHEQUEO GENERAL HECHO POR SU DOCTOR.

Su participación es voluntaria. Tiene el derecho de rehusar o no tomar parte en este estudio. Si decide participar, tiene el derecho de dejar su participación en el futuro en cualquier momento.

Qué sucede en este Estudio de Investigación

Usted será una de aproximadamente 520 personas a quienes se les pedirá participar en este estudio. Toda o parte de la investigación tendrá lugar en la siguiente localidad (es): Centro Médico de la Universidad de Boston. Su examen se llevará a cabo en las facilidades del Estudio del Corazón de Framingham, localizado en 73 Mount Wayte Avenue, en Framingham, Massachusetts o en otras facilidades o residencias.

Nuevas pruebas:

1) Con su permiso, se van a procesar células blancas (tomadas de las muestras de sangre durante su examen aquí) para que imiten el funcionamiento de las células de otros órganos de su cuerpo; como células del hígado, células grasas del corazón y células de los nervios. A estas células que han sido procesadas se les conoce como Células Pluripotenciales Inducidas. Estas células pueden ser estudiadas en laboratorios para aprender más sobre las causas de enfermedades de esos órganos así como las causas de su buena salud. Los investigadores del Estudio del Corazón de Framingham jamás alterarán células para que imiten células reproductivas.
2) Le preguntaremos si podemos obtener células de la parte interna de su mejilla, raspando suavemente con un cepillo de plástico. Las células se usarán para examinar cómo algunos cambios en el ADN (llamados metilación del ADN) se pudieran relacionar con la función pulmonar y otras enfermedades.
3) Se le preguntará si desea usar un pequeño monitor para medir la actividad física. Se usa con un cinturón suave durante una semana y después se le pide que lo envíe por correo al Estudio del Corazón de Framingham. Mide su actividad diaria.

4) Se le preguntará si desea participar en un estudio de colección de orina durante 24 horas, usando un equipo especial de plástico que se le enviará por correo cuando a usted le convenga después de participar aquí.

Otros componentes del estudio por los que ya nos ha dado consentimiento en el pasado. Además de las nuevas pruebas descritas arriba, se harán las siguientes pruebas que ya ha hecho:

1) Historial Médico.
2) Examen físico, incluyendo electrocardiograma o ECG
3) Colección de sangre (hasta 117.5 cc o cuatro onzas) y muestra de orina para hacer pruebas sobre factores de riesgo de las enfermedades y condiciones de salud que están siendo investigadas.
4) Estudios Genéticos: Se le preguntará si se puede usar una parte de su muestra de sangre para más estudios genéticos.
5) Prueba de la Función Vascular: a) Tonometría Arterial, mide la rigidez de las arterias. Junto con una vista limitada de la aorta (la arteria mayor que lleva el flujo de sangre desde la base del corazón), se obtiene una onda colocando un sensor plano sobre las arterias en el brazo (braquial y radial), la ingle (femoral) y el cuello (carótida).
6) Prueba de la función pulmonar; se hace respirando de un tubo conectado a una máquina que mide el volumen y flujo del aire exhalado. A algunos participantes se les pedirá que repitan la prueba usando un inhalador para mejorar el flujo del aire.
7) Cuestionarios sobre su memoria, estados de ánimo y función física, así como dieta y ejercicio.
8) Presión arterial en brazos y tobillos.

   En caso de que llegue a sufrir un derrame cerebral, se le examinará durante su hospitalización (si es pertinente) y a los 3, 6, 12 y 24 meses. El examen incluirá una evaluación neurológica y una evaluación de su habilidad para realizar las actividades.

9) Registros médicos: Se le pedirá que firme una forma para dar permiso al Estudio del Corazón de Framingham a que obtenga copias de registros de hospital, Medicare (CMS) y otros registros médicos. Este permiso es válido para obtener registros médicos a menos que usted lo cancele. Se le pedirá su número de seguro social con el propósito de localizarlo en el futuro. Puede rehusar esta solicitud nuestra. También se le preguntará si investigadores, así como sus colaboradores de investigación en otros institutos, en este caso la Universidad de Duke, pueden relacionar su número de seguro social a la base de datos de CMS para obtener información de Medicare. Los números de seguro social no serán dados a ninguna otra institución.

10) Algunos de los resultados serán enviados a usted y/o a su doctor dentro de seis semanas después de su examen. Sin embargo, hay otras pruebas que pueden requerir meses, incluso años antes de que se pueda enviar algún resultado, porque son parte de proyectos especiales de investigación.

11) Seguimiento: Posiblemente se le contacte en el futuro, ya sea por correo o por teléfono, para obtener más información de su salud o para que se le invite a participar en otros estudios de salud del Estudio del Corazón de Framingham, y para volver a venir a otro examen en el futuro.

Riesgos y Molestias

No esperamos que sucedan riesgos o daños inesperados como resultado de su participación, pero en el extremo caso de que durante su examen usted requiriera atención médica, contamos con primeros auxilios.

Muestra de Sangre: Son posibles un pequeño moretón, dolor, sangrado o en raras ocasiones, infección.

Recolección de células del interior de la mejilla: algunas personas podrían experimentar una sensación de vomito y/o una irritación menor por un corto periodo de tiempo.

La Prueba de la Función Pulmonar involucra un nivel muy bajo de riesgo. Usted podría sentirse mareado o desmayarse y arriesgarse a sufrir una lesión si se cayera. Los participantes a quienes se les haya pedido que inhalen albuterol durante la prueba pulmonar, podrían experimentar un incremento en los latidos del corazón (pulso) o síntomas de agitación o temblores. Las mujeres que estén embarazadas, ya sea determinado por ellas mismas o por una prueba de embarazo, serán excluidas de la segunda parte de la función pulmonar, la cual incluye inhalar albuterol.

Otras molestias incluyen dolores de cabeza, sentirse hambriento por estar ayunando, cansancio y tener frío durante la visita. El examen toma tiempo y es repetitivo. La colección de orina de 24 horas puede ser inconveniente.

Se toman todas las medidas para proteger la seguridad de su información en el estudio. En lugar de nombres, se usan números de identificación en la gran mayoría de las bases de datos. Se utilizan protecciones con bloqueos y claves en los sistemas computacionales. Sin embargo, aun así hay un mínimo riesgo de que se quebrante la confidencialidad.

En las pruebas genéticas existe el riesgo potencial de descubrir y transmitir información indeseada respecto a tener ciertas enfermedades o el riesgo a desarrollarlas. En algunas ocasiones, el saber los resultados de pruebas de ADN puede provocar ansiedad y puede influenciar decisiones respecto a matrimonio y planeación familiar.

Tanto leyes estatales de Massachusetts como una nueva ley Federal llamada El Acta para la No-Discriminación de Información Genética (GINA, por sus siglas en inglés) generalmente hacen ilegal que compañías de seguros, grupos de planes de salud y la mayoría de los empleos discriminen a cualquier persona por su información genética. Estas leyes lo protegerán de la siguiente forma:

1. *Compañías de seguro medico y grupos de planes de salud, no pueden pedir la información genética que obtenemos en este estudio.*

2. *Compañías de seguro medico y grupos de planes de salud no pueden usar su información genética para hacer decisiones respecto a su elegibilidad o primas.*

3. *Empleos con 6 o mas empleados no podrán usar la información genética obtenida de este estudio para hacer decisiones en cuanto a emplearlo, promoverlo o despedirlo, o al reglamentar estatutos en cuanto a su empleo.*

Todas las compañías de seguro medico y grupos de planes de salud deberán seguir la ley de GINA para el 21 de mayo de 2010. Empleos con 15 o más empleados deberán seguir la ley de GINA para el 21 de noviembre de 2009. La ley de Massachusetts la aplica a empleos de 6 o más empleados.

Esté en aviso que ni la ley de Massachusetts ni la nueva ley Federal lo protegen contra discriminación genética de compañías que venden seguros de vida, seguros de incapacidad o seguros de cuidados médicos a largo plazo. Por lo tanto, seguros de vida, seguros de incapacidad y seguros de cuidados médicos a largo plazo tienen el derecho a preguntarle si ha tenido pruebas genéticas y si se rehúsa contestar esta pregunta, pueden negarle la cobertura.

Quizá existan riesgos y molestias desconocidos por el momento. Los empleados del estudio le actualizarán oportunamente sobre cualquier información nueva que pudiera afectar su salud, su bienestar y su decisión de seguir en el estudio.

Posibles Beneficios

Usted no recibirá ningún beneficio directo de su participación en este estudio. Sin embargo, su participación puede ayudar a los investigadores a comprender mejor las causas y prevención de enfermedades cardiovasculares y otras condiciones médicas, incluyendo el potencial de factores genéticos.

Alternativas

Tiene la alternativa de no participar en el estudio.

Costos y pagos

A usted no se le pagará ni se le cobrará por ninguna parte del examen. Si en su examen se descubre algún problema médico que requiera un diagnóstico o tratamiento, se le dará aviso y esta información también se le dará al doctor o a la clínica que usted nos indique. Si su doctor decide que usted debe someterse a más exámenes clínicos o más tratamientos, usted o una tercera persona (por ejemplo su seguro médico o Medicare) serán responsables del costo. No se harán arreglos especiales por compensaciones o pagos de tratamientos por el solo hecho de haber participado en este estudio. Con este párrafo usted no renuncia a sus derechos legales. Los gastos que puede incurrir el día de su participación incluyen, pero no se limitan a, pérdida de horas de trabajo y transportación (gasolina, peaje, etc.). A usted no se le pagará por participar en el estudio.

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Descubrimientos Patentables

Puede ser que algún día las investigaciones de este estudio den como resultado nuevos procedimientos para diagnosticar o curar enfermedades. También puede llevarnos al desarrollo de nuevas medicinas para curar o prevenir enfermedades. Como sucede con toda investigación patrocinada federalmente, los investigadores y sus empleados tienen el permiso por ley, de patentar descubrimientos por los que podrían ser pagados. El Congreso de los Estados Unidos opina que el permitir tales patentes, podría incrementar la posibilidad de que un beneficio de salud pública se lleve a cabo a través del patrocinio federal para la investigación.

Confidencialidad

La información obtenida de usted será tratada como confidencial. Se le asignará un código a usted y a la información que obtengamos de usted. Los códigos solo se darán a investigadores calificados, pero su nombre y otros datos personales no serán proveídos. El riesgo en proveer muestras es mínimo. Las muestras serán guardadas hasta que ya no sirvan para la investigación científica. Usted no será informado de forma rutinaria sobre los resultados de las investigaciones hechas con su material genético, sin embargo, con su permiso, podrá ser informado de algunos hallazgos sobre genética, enfermedades cardiovasculares y otras condiciones de salud generadas por los análisis de su ADN, ya sea directamente o a través de las publicaciones en los boletines.

Cuando los resultados basados en su información sean publicados, su nombre y cualquier otra información que lo pudiera identificar, no serán revelados. Es posible que la información de este estudio, así como de sus registros médicos, sean revisados y fotocopiados por agencias de reglamento estatal o federal, como son: el Comité de Protección de Sujetos Humanos y el Comité de Revisión Institucional del Centro Médico de la Universidad de Boston.

Para ayudarnos a proteger aún más su privacidad, los investigadores han obtenido un Certificado de Confidencialidad del Departamento de Salud y Servicios Humanos (DHHS, por sus siglas en ingles). Con este certificado, los investigadores no pueden ser forzados (por ejemplo por alguna corte) a divulgar información de la investigación que lo pudiera identificar en ningún procedimiento federal, estatal, local civil, criminal, administrativo, legislativo u otros. Sin embargo, será necesaria la divulgación si fuera requerida para hacer una auditoría por parte del DHHS o con propósitos de evaluación del programa. Un Certificado de Confidencialidad no le previene a usted ni a su familia de suministrar voluntariamente su propia información, ni la de su participación en este estudio. Tome nota que si por ejemplo, un asegurador o empleador sabe que usted es participante de este Estudio, y obtiene su consentimiento para obtener más información, en ese caso el investigador no podrá usar el Certificado de Confidencialidad para no divulgar su información. Esto significa que usted y su familia también deben proteger su propia privacidad. Finalmente, por favor comprenda que el investigador no está prevenido de tomar las medidas necesarias (incluyendo reportar a autoridades) para prevenir daños severos a usted mismo y a otros.

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Por favor cheque las casillas correspondientes para indicar si está o no está de acuerdo con lo siguiente:

1) l__l SI l__l NO (Código de Oficina 0)
Estoy de acuerdo en participar en el examen clínico del Estudio del Corazón de Framingham, colección de sangre, células del cachete y orina, y en estudios de factores que contribuyen a enfermedades del corazón, las arterias, los pulmones y la sangre, accidentes cerebro-vasculares, pérdida de memoria, cáncer y otras enfermedades graves y condiciones de salud.

2) l__l SI l__l NO (Código de Oficina 3)
Estoy de acuerdo en permitir que mi información de datos, células del interior de mi cachete y muestras de sangre y orina se usen en futuros estudios genéticos de factores que contribuyen a enfermedades del corazón, las arterias, los pulmones y la sangre, accidentes cerebro-vasculares, pérdida de memoria, cáncer y otras enfermedades y condiciones de salud.

3) l__l SI l__l NO (Código de Oficina 12)
Estoy de acuerdo en permitir que mi información de datos, células del interior de mi cachete, muestras de sangre, orina y ADN se usen en futuros estudios genéticos concernientes a la reproducción y salud mental como alcoholismo y síntomas de depresión.

4) l__l SI l__l NO (Código de Oficina 13)
Estoy de acuerdo en proveer una muestra de sangre para que se formen células pluripotenciales inducidas y con ellas hacer otros tipos de células, como ARN, proteínas y metabolitos. Esto significa que las células blancas de mi sangre se pueden procesar para obtener células madre y luego ser alteradas para que funcionen como células de otros órganos del cuerpo, como: hígado, células grasas, células del corazón y de los nervios.

5) l__l SI l__l NO (Código de Oficina 4)
Estoy de acuerdo en conceder a investigadores de compañías privadas el acceso a mis muestras de orina, sangre, ADN, otra información genética e información de datos en el futuro, que podrían ser utilizados en pruebas de laboratorio o tratamientos que podrían beneficiar a mucha gente. (Nota: ni usted ni sus familiares se beneficiarán económicamente por esto, tampoco su ADN será vendido a nadie).

6) l__l SI l__l NO (Código de Oficina 30)
Estoy de acuerdo en dar permiso al Estudio del Corazón de Framingham para que informe los resultados de mis exámenes no-genéticos y exámenes a mi doctor, clínica u hospital.

7) l__l SI l__l NO (Código de Oficina 31)
Si se identifica alguna condición genética que tuviera importantes implicaciones para mí sobre mi salud y tratamientos, estoy de acuerdo en permitir que el Estudio del Corazón de Framingham me lo notifique y con mi permiso, a mi doctor.

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Derechos del participante

Al darnos su consentimiento para participar en este estudio, usted no cancela ninguno de sus derechos legales. Dar consentimiento significa que usted ha escuchado o leído la información sobre este estudio y que está de acuerdo en participar. Se le dará una copia de esta forma.

Si en cualquier momento decidiera no seguir participando en este estudio, no sufrirá ningún tipo de penalidad ni perderá ningún beneficio al que tuviera derecho.

Puede obtener más información sobre sus derechos como sujeto en el estudio llamando al Comité de Revisión Institucional del Centro Médico de la Universidad de Boston al 617-638-7207.

El investigador o algún miembro del equipo de investigadores tratará de responder a todas sus preguntas. Si tiene preguntas o dudas o si necesita reportar una herida que haya ocurrido mientras participó en el estudio, por favor contacte al Dr. PHILIP WOLF o al Dr. DANIEL LEVY al 508-872-6562 (en inglés).

Compensación por daños relacionados con la Investigación

Si piensa que ha sido herido por participar en este estudio, por favor déjeselo saber al investigador inmediatamente. Si su participación es en el Centro Médico de Boston, puede obtener tratamiento por la herida en el Centro Médico de Boston. Si su participación NO es en el Centro Médico de Boston, pregúntele a su investigador dónde puede obtener tratamiento localmente por su herida. El Centro Médico de la Universidad de Boston y su benefactor, no ofrecen programas para proveer compensación por el costo de cuidados médicos en caso de heridas ocurridas durante el estudio, ni otros gastos como pérdida de dinero por no trabajar, incapacidad, dolor o molestias. Se le enviará la cuenta por el tratamiento recibido si su seguro médico no paga por sus cuidados médicos. Usted no cancela sus derechos legales por firmar esta forma.

Sus Derechos a Rehusar o Descontinuar

Su participación en este estudio es voluntaria. Tiene el derecho de rehusar tomar parte en este estudio. Si decide participar y luego cambia de opinión, puede salirse del estudio. Su participación es completamente voluntaria. Su decisión no afectará el poder obtener cuidado médico en el Centro Médico de Boston, ni los pagos por su cuidado médico. No afectará su enrolamiento a ningún plan de salud o beneficios que pueda obtener. Si decide participar, tiene el derecho a descontinuar en cualquier momento. Si durante el estudio hubiera descubrimientos que pudieran afectar su buena voluntad de participar, se lo harán saber lo más pronto posible.
Es posible que el investigador decida descontinuar su participación sin su permiso porque pudiera decidir que continuar en el estudio sería malo para usted, o porque el patrocinador interrumpa el estudio.

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Información de Salud para Protección de Sujetos

Usted tiene ciertos derechos relacionados con su información de salud. Estos incluyen el derecho a saber quién obtendrá su información de salud y para qué se utilizará. Si decide tomar parte en este estudio de investigación, obtendremos información sobre usted según se indica a continuación.

INFORMACION DE SALUD DE USTED QUE PUEDE SER USADA O DADA A OTROS DURANTE ESTE ESTUDIO:

- Información de su hospital o registros médicos de BUMC/BMC (Centro Médico de la Universidad de Boston) o de otra parte. Esta información es razonablemente relacionada al propósito del estudio de investigación. Si se necesitara información de sus doctores u hospitales fuera de BUMC/BMC, se le pedirá que nos dé permiso para que estos registros sean enviados al investigador del estudio.

- Nueva información que se obtenga de pruebas, procedimientos, visitas, entrevistas o formas completadas como parte de este estudio.

RAZONES POR LAS QUE ES POSIBLE QUE DEMOS SU INFORMACION DE SALUD A OTROS
Las razones por las que es posible que usemos o compartamos su información de salud son:

- Para hacer el estudio descrito aquí.
- Para asegurarnos de llevar a cabo el estudio de acuerdo con ciertos estándares de ética, la ley y grupos de control.

GENTE Y GRUPOS QUE PUDIERAN USAR O DAR SU INFORMACION DE SALUD

1. GENTE O GRUPOS DENTRO DE BUMC/BMC

- Investigadores involucrados en el estudio
- La Mesa Institucional de Revisión del Centro Médico de la Universidad de Boston que supervisa este estudio.

2. GENTE O GRUPOS FUERA DE BUMC/BMC

- Gente o grupos que empleamos para hacer ciertos trabajos, como compañías de almacenamiento de información de datos o laboratorios.
- Agencias federales y estatales si lo requiere la ley o si están involucradas con la supervisión del estudio. Estas agencias pueden incluir el Departamento de Salud y Servicios Humanos de Estados Unidos, La Administración de Alimentos y Drogas, Los Institutos Nacionales de Salud, y el Departamento de Salud de Massachusetts.
- Organizaciones que aseguran que los estándares de los hospitales se mantengan.
- El o los Benefactores del estudio, y gente o grupos que emplean para ayudarles a realizar la investigación.
- Otros investigadores que forman parte de este estudio.
- Un grupo que supervisa la información de la investigación y la seguridad de este estudio.
  Otros:

Puede que alguna gente o grupos que obtengan su información de salud no sigan las mismas reglas de privacidad que seguimos. Compartimos su información de saludo sólo cuando es indispensable. Pedimos a quienes la obtengan que protejan su privacidad como participante. Sin embargo, una vez la información sale de BUMC (Centro Médico de la Universidad de Boston), no podemos prometer que la información se mantenga privada. En la mayoría de los casos, cualquier información que es dada a otros, se identifica con un número único de estudio, y no con su nombre. Así que, aunque pudiera ser posible relacionar el número con su información, esto usualmente no sucede.

PERIODO DE TIEMPO PARA USAR O DAR SU INFORMACION DE SALUD

Dado que los estudios de investigación son un proceso continuo, no podemos darle una fecha exacta sobre cuándo su información de salud será destruida o se dejará de usar o compartir.

SUS DERECHOS A LA PRIVACIDAD

- Usted tiene el derecho a no firmar esta forma que nos permite usar y compartir su información de salud para investigación. Si no firma esta forma, no puede participar en el estudio, ya que necesitamos usar su información de salud para poderla estudiar.
- Tiene el derecho de detener su permiso para usar o compartir su información de salud en este estudio de investigación. Si así lo desea, debe escribir una carta a los investigadores encargados de este estudio de investigación. Si deja de darnos permiso, no podrá tomar de vuelta la información que ya ha sido usada o compartida con otros. Esto incluye información usada o compartida con propósitos de investigación o para garantizar la seguridad y calidad del estudio. Si retira su permiso, no puede continuar en el estudio.
- Tiene el derecho de ver y obtener una copia de la información de salud que es usada o compartida para uso de investigación. Sin embargo, solo puede obtener esto cuando la investigación haya terminado. Para pedir esta información, por favor contacte a la persona encargada de este estudio de investigación.

EN CASO DE QUE LOS RESULTADOS DEL ESTUDIO SEAN USADOS PARA SER PUBLICADOS O PARA LA ENSEÑANZA

Los resultados del estudio podrían ser publicados en alguna revista o libro médicos, o usados para enseñar a otros. Sin embargo, su nombre u otra información que lo pudiera identificar, no será usada sin su permiso específico.

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Firmar esta forma de consentimiento indica que usted ha leído esta forma (o se la han leído), que sus preguntas han sido contestadas a su satisfacción y que usted voluntariamente accede a participar en este estudio de investigación. Usted recibirá una copia firmada de esta forma de consentimiento.

Firma del Participante	Nombre con Letra de Molde	Fecha
Representante legal autorizado (LAR) firma y nombre con Letra de Molde		Fecha
Firma de la Persona que Obtiene el Consentimiento y Nombre		Fecha

RESEARCH CONSENT FORM

OMNI Generation II Exam 2

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

Background

You are participating in the Framingham Heart Study Omni Generation 2. The Framingham Heart Study (FHS) is an observational study to find relationships between risk factors, genetics, heart and blood vessel disease, and other health conditions over three generations. You are signing this consent form to cover your participation for all future exam cycles of the FHS. You may withdraw your participation from any single exam cycle or the whole study at any time. You will not be required to sign another consent form unless a new procedure is added. At each future exam cycle you will be provided an information sheet containing information about what will occur during that exam cycle.

Purpose

The purpose of this research is to:

1) investigate factors related to the development of heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, osteoporosis, cancer and other major diseases and health conditions; and

2) examine DNA and its relationship to the risks of developing these diseases and other health conditions.

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

What Happens In This Research Study

You will be one of approximately 410 subjects to be asked to participate in this study.

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

Your research examination will take place at the FHS at 73 Mt. Wayte Avenue in Framingham, MA, or may take place in your home or other 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, emergency room visits, surgeries, physician visits, reproductive history, personal and family history, and health habits (including diet, exercise, prescription and non-prescription drug use, smoking and alcohol use).

2) Measurements and Procedures: A FHS 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 blood pressure in both arms and legs if you are 40 years old or older). Your lung function will be measured by breathing in and out of a machine. Some participants will be asked to inhale a bronchodilator medication (albuterol) used routinely in lung function testing, and then to repeat some of the tests. You will be asked in a recorded interview questions about your mood, memory, and mobility. Your hand grip strength, balance, and walking speed will be measured. You will also be asked to wear a small accelerometer to count your footsteps and measure your physical activity over the course of a week.

In the event that you may have a stroke, you would be examined during your hospitalization (if applicable) and at 3, 6, 12 and 24 months. The examination would include a neurological evaluation and an assessment of your ability to perform daily activities.

3) Blood and urine specimens: A technician will draw a sample of your blood (110 cc or about 7.5 tablespoons). You will be asked to take a standard glucose tolerance test which involves swallowing a sweet drink and taking a second blood sample two hours later (this test will not be given to anyone known to have diabetes). You will be asked to give a sample of your urine. Both the blood and urine samples will be used to test for risk factors for the diseases and health conditions under investigation. As part of the bone density test, described below, all women under the age of 55 years of age, will be asked to take a urine pregnancy test to confirm that they are not pregnant. This will also be required for women over the age of 55 who have not had a hysterectomy or tubal ligation and whose last menstrual period was less than or equal to 6 months ago. You may choose to withdraw your blood samples from future use and the samples will be destroyed after your request is received. If you choose to withdraw your samples, you should call the lab manager of the FHS at (508) 935-3477.

Genetic Studies: You will be asked if a sample of the blood you have donated may be used to obtain genetic material (for example DNA) for research. Genetic research will include the detailed description of the building blocks of DNA and thus may identify genetic conditions that have important health and treatment implications for you. Neither your name nor clinic number appears on the sample.

Data and DNA will be distributed to the FHS researchers and other qualified researchers interested in the genetics of heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other major diseases and health conditions. The researchers will be given the DNA without any personally identifying information. Knowledge from the research on your DNA may be used to develop new tests or medicines for the diseases and conditions under investigation. Your DNA will not be sold to any person, institution, or company for financial gain or commercial profit. Neither you nor your heirs will gain financially from discoveries made using the information and/or specimens that you provide

4) Vascular function testing: You will be asked to participate in an experimental test of blood vessel function that takes about 15 minutes. 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 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. Images of the aorta (main blood vessel in the body) will be taken to interpret the tonometry test. You will also be asked to lie on a long, narrow sensor placed between your shoulder blades. The sensor warms your skin and uses infrared light to detect the timing of arrival of blood flow to the skin of your back. We use this information to evaluate the stiffness of your aorta, which is the largest artery in your body. You will also be asked to wear electrocardiographic leads to measure your heart rhythm.

5) Bone Density Test: You will be asked to participate in a bone density test that takes approximately 15 minutes. Women will be asked additional questions to determine eligibility for the bone density test. If you are pregnant or might be pregnant, you will not be eligible to have the bone density test today. For those who are eligible, the following tests will be done:

a. A bone density test of your whole body, hip and spine. The bone density test involves lying on a padded table using an x-ray type machine called a bone densitometer to measure the density of your hip and spine bones. Body composition and lean muscle mass will be measured from the whole body scan.

b. A brief questionnaire about your physical activity, any fractures you have had and risk factors for bone loss.

c. Testing of your leg muscle that involves having you push out your leg against a padded muscle-testing device.

6) Medical Records: You will be asked to sign a release form to allow the FHS staff to obtain and review copies of your hospital, cancer registry, Medicare (CMS) and medical records. These copies will be reviewed by the FHS physician investigators. The medical release form is considered valid to obtain these records, and will be valid until canceled by you.

You may be contacted later to obtain additional health information or be invited to participate 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; you may choose to decline this request. You may be asked to come back for another exam. With your permission, a summary letter of routine test results from this exam will be sent

to you and your physician. Any questions you have regarding your rights as a research subject can be directed to the Office of the Institutional Review Board of Boston Medical Center at (617) 638-7207. The FHS 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

Risk or injury, as a result of participation, is not expected. In the unlikely event that during the examination you require medical care, first aid will be available.

The Blood Draw: Minimal bruising, pain, bleeding, or in rare circumstances, an infection may occur.

The Lung Function test involves a low level of risk. You may feel lightheaded or you may faint and risk 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). Pregnant women, as determined by self report or by a positive pregnancy test, will be excluded from the second part of the pulmonary function test, which includes the albuterol challenge.

Bone Density Test:

The risks of the testing are minimal. Having a bone density test involves being exposed to a minimal amount of radiation. The radiation exposure or effective dose, from the combined hip and spine bone density scans equals 2.0 microsievert (μSv). The average effective dose in the U.S. from background radiation is approximately 3000 μSv per year, or about 8 μSv per day. Therefore, the expected total effective dose from a bone density scan done in this study is less than the dose individuals receive every day from background radiation.

If you are a pre-menopausal woman, even though you have had a pregnancy test to be sure you're not pregnant and have been asked questions about the use of birth control during the past week, there is still a very small chance that you could be pregnant. In such a rare instance, the radiation exposure to the fetus would be a potential risk.

Other discomforts include headaches, feeling hungry due to fasting, fatigue and chill during the visit. The exam is time consuming and repetitive. The 24 hour urine collection may be inconvenient.

Safeguards are in place to protect the security of your study information. FHS ID numbers are used on most data files instead of names. Firewalls and password protection are in place on the computer systems. Staff is trained in safe computer practices. However there is still a minimal risk of a breach in confidentiality.

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There is potential risk in genetic testing for uncovering and conveying unwanted information regarding parentage or specific risk of disease. Also, sometimes, knowledge of DNA test results can provoke anxiety and influence decisions regarding marriage and family planning:

Both Massachusetts state laws and a new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally make it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. These laws generally will protect you in the following ways:

1. Health insurance companies and group health plans may not request your genetic information that we get from this research.

2. Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

3. Employers with 6 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow the GINA law by May 21, 2010. All employers with 15 or more employees must follow the GINA law as of November 21, 2009. Massachusetts law currently applies to all employers of 6 or more employees. Be aware that neither Massachusetts law nor the new Federal law protects you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Thus, life insurance, disability insurance and long-term care insurance companies may legally ask whether you have had genetic testing and deny coverage for refusal to answer this question. There may be unknown risks/discomforts involved. Study staff will update you in a timely way on any new information that may affect your health, welfare, or decision to stay in this study

Potential Benefits

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand the frequency, causes (risk factors), and consequences of cardiovascular and other diseases.

Alternatives

Your alternative is to not participate in the study.

Subject Costs and Payments

You will not be charged or paid for any part of the examination. If the examination finds medical

problems that require tests or treatments, you will be so advised and that information will be provided to the physician or clinic that you choose. If your physician decides that follow up tests or treatments are necessary, payment must be provided by you or a third party payer (for example, health insurance or Medicare). No special arrangement will be made by the Framingham Heart Study for compensation or payment solely because of your participation in this study. This does not waive any of your legal rights. Costs that you may 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

Information obtained about you will be treated as confidential; a code number will be assigned to you and your data. The codes will only be provided to qualified investigators. The risk in providing this sample is minimal. Your samples will be kept until they are not of scientific value. You will not be routinely informed of results of the research performed upon your genetic samples, although with your permission you may be informed of some findings about genetics, cardiovascular disease or other health conditions generated from DNA analyses, directly or through publication in newsletters. Genetic tests may be developed as a result of the analysis of samples in the FHS.

When study results are published, your name and other identifying information will not be revealed. Information from this study and from your medical record may be reviewed and photocopied by 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. To help us further protect your privacy, the investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

A Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer or employer obtains your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy. Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

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Please check the appropriate box above each of the following statements:

1) |___| YES |___| NO (Office Code 0) I agree to participate in the FHS clinic examination and studies of the factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other major diseases and health conditions.

2) |___| YES |___|NO (Office Code 3) I agree to provide a blood sample from which genetic material (DNA and other components) can be obtained. I agree to allow my data and blood samples to be used in the genetic studies of factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other diseases and health conditions.

3) |___| YES |___| NO (Office Code 1) 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.)

4) |___| YES |___| NO (Office Code 12) I agree to allow my data and blood samples to be used in genetic studies of reproductive conditions, and mental health conditions such as alcohol use and depressive symptoms.

5) |___| YES |___| NO (Office Code 4) I agree to allow researchers from commercial companies to have access to my DNA and genetic data which may be used to develop new lab tests or treatments that could benefit many people. (You or your heirs will not benefit financially from this, nor will your DNA be sold to anyone.)

6) |___| YES |___| NO (Office Code 30) I agree to allow the FHS to release the findings of non-genetic tests and examinations to my physician, clinic, or hospital.

7) |___| YES |___| NO (Office Code 31) If a genetic condition is identified that may have important health and treatment implications for me, I agree to allow the FHS to notify me and then with my permission to notify my physician.

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Subject's Rights

By consenting to participate in this study you do not waive any of your legal rights. Giving consent means that you have heard or read the information about this study and that you agree to participate. You will be given a copy of this form to keep.

If at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled.

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

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury while participating in this research, contact Emelia J. Benjamin, MD, ScM or Daniel Levy, MD 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.

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

Participant's Signature	**Printed Name**	**Date**
Legally Authorized Representative (LAR)'s Signature	**Printed Name**	**Date**
Person Obtaining Consent Signature	**Printed Name**	**Date**
Witness' Signature	**Printed Name**	**Date**

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Antecedentes
Usted está participando en el Estudio del Corazón de Framingham para Omni Gen 2. El Estudio del Corazón de Framingham (FHS por sus siglas en Inglés) es un estudio de observación para identificar la relación entre factores de riesgo, genética, enfermedades cardiovasculares y otras condiciones de salud por tres generaciones. Se le está pidiendo que firme esta forma de consentimiento para cubrir su participación en los exámenes futuros dentro de este ciclo del FHS. En cualquier momento, usted puede decidir no participar en alguna parte del examen o dejar de participar por completo. No se le pedirá que firme otra forma de consentimiento a menos que se añada algún otro procedimiento. En el futuro, cada vez que participe en otro ciclo del examen, se le dará una hoja con información sobre lo que ocurrirá en ese examen.

Propósito
El propósito de este estudio es

1) investigar los factores relacionados con el desarrollo de enfermedades del corazón y las arterias, enfermedades del pulmón y la sangre, accidentes cerebro-vasculares, pérdida de memoria, pérdida de densidad ósea, cáncer y otras enfermedades y condiciones de la salud.

2) examinar el ADN y su relación con los riesgos a desarrollar estas enfermedades y otras condiciones de la salud.

ESTE EXAMEN NO TOMA EL LUGAR DE UNA REVISION GENERAL HECHA POR SU DOCTOR.

Qué sucede en este Estudio de Investigación
Usted será una de aproximadamente 410 personas a quienes se les pedirá participar en este estudio.

Su estudio de investigación tendrá lugar en la siguiente localidad: Centro Médico de la Universidad de Boston.
Su examen en particular, se llevará a cabo en las facilidades del Estudio del Corazón de Framingham, localizado en 73 Mount Wayte Avenue, en Framingham, Massachusetts o en otras facilidades o residencias. El examen tomará aproximadamente 4 horas e incluye lo siguiente:

1) Historial.

Una entrevista de sus condiciones médicas del pasado y el presente incluyendo enfermedades del corazón y los pulmones, hospitalizaciones, visitas a la sala de emergencias, cirugías, visitas al doctor, historial reproductivo, historial médico personal y familiar y hábitos generales médicos y de salud (incluyendo dieta, ejercicio, uso de medicinas prescritas y no prescritas, drogas, cigarros, y alcohol).

2) Medidas y Procedimientos.

Un doctor del Estudio del Corazón de Framingham le hará un examen físico. Se le tomarán las medidas físicas como lo hacen de rutina en la oficina de su doctor: altura, peso, presión arterial

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(incluyendo la presión arterial en ambos brazos y piernas si tiene 40 años de edad o más). Se medirá su función pulmonar pidiéndole que inhale y exhale en una máquina. A algunos participantes se les pedirá que inhalen un broncodilatador (Albuterol) usado normalmente en pruebas del funcionamiento de los pulmones, y luego se les pedirá que repitan algunas de estas pruebas. En una entrevista grabada, se le preguntará sobre sus estados de ánimo, memoria y actividad. Se medirá la fuerza en sus manos, su balance y la velocidad con que camina. Se le pedirá que use un acelerómetro para contar sus pasos y medir su actividad física en el curso de una semana.
En caso de que llegue a sufrir un derrame cerebral, se le examinará durante su hospitalización (si es pertinente) y a los 3, 6, 12 y 24 meses. El examen incluirá una evaluación neurológica y una evaluación de su habilidad para realizar las actividades.

3) Especímenes de sangre y orina.
Un técnico le tomará una muestra de sangre (110 cc o el equivalente a 7.5 cucharadas). Se le hará una prueba de tolerancia de glucosa en la que debe tomar una bebida dulce. Después de dos horas se le tomará otra muestra de sangre para ver la tolerancia a la glucosa (esta prueba no se hará a las personas que sepan que tienen diabetes). También se le pedirá que nos dé una muestra de orina. Ambas muestras serán usadas para examinar potenciales factores de riesgo de las enfermedades y condiciones de salud que están siendo investigadas. Como parte del estudio de densidad ósea, a las mujeres de menos de 55 años de edad se les hará una prueba de embarazo con la orina, para confirmar que no estén embarazadas. Esto también se les pedirá a las mujeres de más de 55 años que no hayan tenido una histerectomía, ligación de tubos y que su último período menstrual haya sido en menos de seis meses. Usted puede elegir que se destruyan sus muestras para uso futuro en la investigación. En ese caso las muestras serán destruidas cuando recibamos su petición. Si elige retirar sus muestras, por favor contacte a la administradora del laboratorio del Estudio del Corazón de Framingham, al 508-935-3477 (en Ingles) o para Español, contacte a la Coordinadora de Omni, Paulina Drummond, al 508-935-3485.

Estudios Genéticos: Se le preguntará si se puede usar una porción de su sangre donada para obtener material genético (como ADN) para investigación. La investigación genética incluirá la descripción detallada de los bloques de ADN y por lo tanto se podrían identificar condiciones genéticas que tuvieran importantes implicaciones sobre su salud y los posibles tratamientos. Ni su nombre ni su número de identificación en la clínica aparecerán en estas muestras.
La información de datos y el ADN serán distribuidos a investigadores del Estudio del Corazón de Framingham y a otros investigadores calificados interesados en la genética de enfermedades cardiovasculares, del pulmón y la sangre, derrames cerebrales, pérdida de memoria, cáncer y otras condiciones graves de la salud. El ADN será dado a los científicos de los laboratorios sin ninguna información que pueda identificar al donante. Los conocimientos obtenidos de la investigación de su ADN podrán ser usados en el desarrollo de procedimientos para diagnosticar tales enfermedades y para el desarrollo de nuevos tratamientos. Su ADN no será vendido a nadie ni se dará a instituciones o

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compañías que obtengan beneficio monetario o provecho comercial. Sin embargo, ni usted ni sus familiares obtendrán beneficios monetarios por descubrimientos hechos usando la información y/o especimenes que usted nos dé.

4) Prueba de la función vascular.
Se le pedirá participar en una prueba experimental de la función vascular que tomarán cerca de 15 minutos. La tonometría arterial mide el endurecimiento de las arterias registrando cuidadosamente las ondas de la presión arterial. Un técnico hará esta evaluación usando un tonómetro (sensor de presión arterial plano que cuando se presiona ligeramente sobre la piel donde está la arteria, registra las ondas). Las arterias estudiadas con tonometría serán en el cuello (carótida), en el brazo (braquial y radial), y en la ingle (femoral). También se le pedirá que se recueste sobre un sensor alargado que se colocará entre sus hombros. El sensor calienta la piel y usa luz infrarroja para determinar cuánto tiempo tarda la sangre en llegar a la piel de su espalda. Usamos esta información para evaluar la rigidez de la aorta, la arteria más grande del cuerpo. También le pondremos placas electrocardiográficas para medir el ritmo cardiaco.

5) Prueba de Densidad ósea. Se le pedirá que participe en esta prueba que durará aproximadamente 15 minutos. A las mujeres se les harán preguntas adicionales para determinar elegibilidad para esta prueba. Si está embarazada o pudiera estarlo, no podrá ser elegible para esta prueba hoy. Para quienes sean elegibles se llevarán a cabo los siguientes exámenes:

a. Una prueba de densidad ósea general del cuerpo, y de cadera y columna. Esto involucra que se acueste en una tabla acolchonada. Se usa una máquina de rayos-x llamada densitómetro para medir la densidad ósea de la cadera y columna vertebral. La composición del cuerpo y de los músculos será medida con el scan general del cuerpo.
b. Un corto cuestionario sobre su actividad física, fracturas de hueso que haya tenido y factores de riesgo de pérdida ósea.
c. Probaremos los músculos de sus piernas, haciéndole que empuje las piernas hacia afuera contra un aparato para medir la fuerza muscular.

6) Registros Médicos. Se le pedirá que firme una forma adicional para autorizar que el personal del Estudio del Corazón de Framingham pueda obtener y revisar copias de su hospital, registros de cáncer (si hubiera), Centros Medicare y Servicios Medicaid (CMS, por sus siglas en inglés) y registros médicos. Estas copias serán revisadas por los investigadores del Estudio del Corazón de Framingham. Esta forma de autorización se considerará válida para obtener récords médicos y el permiso será válido hasta que usted lo cancele.

Es posible que se le contacte mas tarde para obtener información adicional sobre su salud o para ser invitado a participar en otros estudios de salud relacionados al Estudio del Corazón de Framingham. Se le pedirá su número de seguro social (opcional) con el propósito de poder localizarlo en el futuro. Puede rechazar esta petición. Puede pedírsele que regrese para otro examen. Si lo desea, con su

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autorización, se le enviará a usted y a su doctor, una carta con el resumen de los resultados de esta prueba. Cualquier pregunta que tenga respecto a sus derechos como sujeto en el estudio podrán ser dirigidos al Comité de Protección de Derechos Humanos del Centro Médico de Boston al 617-638-7207. El Estudio del Corazón de Framingham es un proyecto de investigación médica patrocinado por el Instituto Nacional de la Salud bajo la autorización 42USC 285b-3. El sistema de registro que utiliza el Estudio del Corazón de Framingham está documentado en el Registro Federal, Septiembre 26, 2002 (Vol. 67, No. 1879) páginas 60770-60780.

Riesgos y Molestias

No esperamos que sucedan riesgos o daños inesperados como resultado de su participación, pero en el extremo caso de que durante su examen usted requiriera atención médica, contamos con primeros auxilios.

Muestra de Sangre: Son posibles un pequeño moretón, dolor, sangrado o en raras ocasiones, infección.

La Prueba de la Función Pulmonar involucra un nivel muy bajo de riesgo. Usted podría sentirse mareado o desmayarse y arriesgarse a sufrir una lesión si se cayera. Los participantes a quienes se les haya pedido que inhalen albuterol durante la prueba pulmonar, podrían experimentar un incremento en los latidos del corazón (pulso) o síntomas de agitación o temblores. Las mujeres que estén embarazadas, ya sea determinado por ellas mismas o por una prueba de embarazo, serán excluídas de la segunda parte de la función pulmonar, la cual incluye inhalar albuterol.

Prueba de Densidad ósea: Los riesgos son mínimos. La prueba de densidad ósea involucra el estar expuesto a una cantidad mínima de radiación. La exposición a radiación o dosis efectiva de la combinación de los scans de la vertebra y la cadera, suman 2.0 microsievert (μSv) al día. EL promedio de dosis efectiva de radiación ambiental es de aprox. 3000 (μSv) por año, o 8 (μSv) al día. Por lo tanto, la dosis efectiva total del scan de densidad ósea hecho en este estudio, es menor que lo que cualquier persona recibe diariamente de radiación ambiental.

Si usted es una mujer pre-menopáusica, incluso si le hicieron la prueba de embarazo para asegurarse que no está embarazada, y le han hecho preguntas sobre el uso de anticonceptivos durante la última semana, aún así podría haber un pequeño riesgo de que pudiera estar embarazada. En este raro caso, la exposición de radiación al feto podría ser un riesgo potencial.

Otras molestias incluyen dolores de cabeza, sentirse hambriento por estar ayunando, cansancio y tener frío durante la visita. El examen toma tiempo y es repetitivo. La colección de orina de 24 horas puede ser inconveniente.

Se toman todas las medidas para proteger la seguridad de su información en el estudio. En lugar de nombres, se usan números de identificación en la gran mayoría de las bases de datos. Se utilizan protecciones con bloqueos y claves en los sistemas computacionales. Sin embargo, aun así hay un mínimo riesgo de que se quebrante la confidencialidad.

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En las pruebas genéticas existe el riesgo potencial de descubrir y transmitir información indeseada respecto a tener ciertas enfermedades o el riesgo a desarrollarlas. En algunas ocasiones, el saber los resultados de pruebas de ADN puede provocar ansiedad y puede influenciar decisiones respecto a matrimonio y planeación familiar.

Tanto leyes estatales de Massachusetts como una nueva ley Federal llamada El Acta para la No-Discriminación de Información Genética (GINA, por sus siglas en inglés) generalmente hacen ilegal que compañías de seguros, grupos de planes de salud y la mayoría de los empleos discriminen a cualquier persona por su información genética. Estas leyes lo protegerán de la siguiente forma:

1. *Compañías de seguro medico y grupos de planes de salud, no pueden pedir la información genética que obtenemos en este estudio.*
2. *Compañías de seguro medico y grupos de planes de salud no pueden usar su información genética para hacer decisiones respecto a su elegibilidad o primas.*
3. *Empleos con 6 o mas empleados no podrán usar la información genética obtenida de este estudio para hacer decisiones en cuanto a emplearlo, promoverlo o despedirlo, o al reglamentar estatutos en cuanto a su empleo.*

Todas las compañías de seguro medico y grupos de planes de salud deberán seguir la ley de GINA para el 21 de mayo de 2010. Empleos con 15 o más empleados deberán seguir la ley de GINA para el 21 de noviembre de 2009. La ley de Massachusetts la aplica a empleos de 6 o más empleados.

Esté en aviso que ni la ley de Massachusetts ni la nueva ley Federal lo protegen contra discriminación genética de compañías que venden seguros de vida, seguros de incapacidad o seguros de cuidados médicos a largo plazo. Por lo tanto, seguros de vida, seguros de incapacidad y seguros de cuidados médicos a largo plazo tienen el derecho a preguntarle si ha tenido pruebas genéticas y si se rehúsa contestar esta pregunta, pueden negarle la cobertura.

Quizá existan riesgos y molestias desconocidos por el momento. Los empleados del estudio le actualizarán oportunamente sobre cualquier información nueva que pudiera afectar su salud, su bienestar y su decisión de seguir en el estudio.

Posibles Beneficios
Usted no recibirá ningún beneficio directo de su participación en este estudio. Sin embargo, su participación puede ayudar a los investigadores a comprender mejor las causas, etiología y prevención de enfermedades cardiovasculares y otras condiciones de la salud, incluyendo el potencial de factores genéticos.

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Alternativas
Tiene la alternativa de no participar en el estudio.

Costos y pagos
A usted no se le pagará ni se le cobrará por ninguna parte del examen. Si en su examen se descubre algún problema médico que requiera un diagnóstico o tratamiento, se le dará aviso y esta información también se le dará al doctor o a la clínica que usted nos indique.

En caso de que su doctor decida que usted debe someterse a más exámenes clínicos o más tratamientos, estos deberán ser pagados ya sea por usted o por una tercera persona (por ejemplo su seguro médico o Medicare). No se harán arreglos especiales por compensaciones o pagos de tratamientos por el solo hecho de haber participado en este estudio. Este párrafo no cancela sus derechos legales. Los gastos que puede incurrir el día de su participación incluyen, pero no se limitan a, pérdida de horas de trabajo y transportación (gasolina, peaje, etc.). A usted no se le pagará por participar en el estudio.

Confidencialidad
La información obtenida de usted será tratada como confidencial. Se le asignará un código a usted y a la información que obtengamos de usted. Los códigos solo se darán a investigadores calificados. El riesgo en proveer muestras es mínimo. Las muestras serán guardadas hasta que ya no sirvan para la investigación científica. Usted no será informado de forma rutinaria sobre los resultados de las investigaciones hechas con su material genético, sin embargo, con su permiso, podrá ser informado de algunos hallazgos sobre genética, enfermedades cardiovasculares y otras condiciones de salud generadas por los análisis de su ADN, ya sea directamente o a través de las publicaciones en los boletines. Podrán desarrollarse pruebas genéticas como resultado de los análisis de las muestras del Estudio del Corazón de Framingham.

Cuando los resultados basados en su información sean publicados, su nombre y cualquier otra información que lo pudiera identificar, no serán revelados. Es posible que la información de este estudio, así como de sus registros médicos, sean revisados y fotocopiados por agencias de reglamento estatal o federal, como son: el Comité de Protección de Sujetos Humanos y el Comité de Revisión Institucional del Centro Médico de la Universidad de Boston. Para ayudarnos a proteger aún más su privacidad, los investigadores han obtenido un Certificado de Confidencialidad del Departamento de Salud y Servicios Humanos (DHHS, por sus siglas en Ingles). Con este certificado, los investigadores no pueden ser forzados (por ejemplo por alguna corte) a divulgar información de la investigación que lo pudiera identificar en ningún procedimiento federal, estatal, local civil, criminal, administrativo, legislativo u otros.

Sin embargo, será necesaria la divulgación si fuera requerida para hacer una auditoría por parte del DHHS o con propósitos de evaluación del programa.

Un Certificado de Confidencialidad no le previene a usted ni a su familia de suministrar voluntariamente

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su propia información, ni la de su participación en este estudio. Tome nota que si por ejemplo, un asegurador o empleador sabe que usted es participante de este Estudio, y obtiene su consentimiento para obtener más información, en ese caso el investigador no podrá usar el Certificado de Confidencialidad para no divulgar su información. Esto significa que usted y su familia también deben proteger su propia privacidad.

Por favor cheque en la casilla apropiada si está o no está de acuerdo con los siguientes estatutos:

1) I__I SI I__I NO (Código de Oficina 0)
Estoy de acuerdo en participar en el examen clínico del Estudio del Corazón de Framingham y en estudios de factores que contribuyen a enfermedades del corazón, las arterias, los pulmones y la sangre, accidentes cerebro-vasculares, pérdida de memoria, cáncer y otras enfermedades graves y condiciones de salud.

2) I__I SI I__I NO (Código de Oficina 3)
Estoy de acuerdo en proveer una muestra de sangre de la que se extraerá material genético (ADN y otros componentes). Estoy de acuerdo que mi información y muestras de sangre se usen en estudios genéticos de factores que contribuyen a enfermedades del corazón, las arterias, los pulmones y la sangre, accidentes cerebro-vasculares, pérdida de memoria, cáncer y otras enfermedades y condiciones de salud.

3) I__I SI I__I NO (Código de Oficina 1)

Estoy de acuerdo que se haga una línea de células de mi sangre para proveer abastos renovables de ADN. Una línea de células es una muestra congelada y especialmente procesada de células blancas de la sangre, permitiendo que se reproduzcan más células blancas y así poder obtener más ADN, según se vaya necesitando para futuros estudios.

4) I__I SI I__I NO (Código de Oficina 12)

Estoy de acuerdo en permitir que mi información de datos y mis muestras sean usadas en estudios genéticos de condiciones concernientes a la reproducción y salud mental, tales como el consumo de alcohol y síntomas depresivos.

5) I__I SI I__I NO (Código de Oficina 4)
Estoy de acuerdo en conceder a investigadores de compañías privadas el acceso a mi ADN e información genética que podría ser utilizada en pruebas de laboratorio para hacer diagnósticos o terapias farmacéuticas que podrían beneficiar a mucha gente. (Nota: Usted o sus familiares no se beneficiarán económicamente por esto, tampoco su ADN será vendido a nadie).

6) I__I SI I__I NO (Código de Oficina 30)

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Estoy de acuerdo en dar permiso al Estudio del Corazón de Framingham para que informe los resultados de mis exámenes no-genéticos y análisis a mi doctor, clínica u hospital.

7) I__I SI I__I NO (Código de Oficina 31)
Si se identifica alguna condición genética que tuviera importantes implicaciones para mí sobre mi salud y tratamientos, estoy de acuerdo en permitir que el Estudio del Corazón de Framingham me lo notifique y con mi permiso, a mi doctor.

Derechos del Participante
Al darnos su consentimiento para participar en este estudio, usted no renuncia a ninguno de sus derechos legales. Dar consentimiento significa que usted ha escuchado o leído la información sobre este estudio y que está de acuerdo en participar. Se le dará una copia de esta forma firmada.

Si en cualquier momento decidiera no seguir participando en este estudio, no sufrirá ningún tipo de penalidad ni perderá ningún beneficio al que tuviera derecho.

Puede obtener mas información sobre sus derechos como sujeto de estudio llamando al Comité de Protección de Derechos Humanos del Centro Médico de Boston al 617-638-7207. Si este estudio se hace fuera de los Estados Unidos, puede pedirle al investigador la información para contactar al Comité de Ética local.

El investigador o algún miembro del equipo de investigadores tratarán de responder a todas sus preguntas. Si tiene dudas o preguntas, o si necesita reportar alguna herida ocurrida durante su participación en esta investigación, por favor comuníquese con la Dra. Emelia Benjamin o con el Dr. Daniel Levy al 508-872-6562 en el Estudio del Corazón de Framingham, 73 Mount Wayte Ave. Suite #2, Framingham, MA 01702.

Compensación por daños relacionados con la Investigación
Si piensa que ha sido herido por participar en este estudio, por favor déjeselo saber al investigador inmediatamente. Si su participación es en el Centro Medico de Boston, puede obtener tratamiento por la herida en el Centro Médico de Boston. Si su participación NO es en el Centro Medico de Boston, pregúntele a su investigador dónde puede obtener tratamiento localmente para la herida. Usted y su seguro médico recibirán la cuenta por el tratamiento recibido. Algunos patrocinadores de investigación ofrecen un programa para cubrir parte de los costos del tratamiento que no son cubiertos por su seguro médico. Debería preguntarle al equipo de investigación si tal programa está disponible.

Sus Derechos a Rehusar o Descontinuar
Su participación en este estudio es voluntaria. Tiene el derecho de rehusar tomar parte del estudio. Si decide participar y después cambia de opinión, puede salirse del estudio. Su participación es totalmente opcional. Su decisión no afectará el cuidado médico que pueda recibir en esta institución ni el pago de su cuidado médico. No afectará su inscripción a seguros médicos o beneficios que pudiera obtener.

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Si decide tomar parte, tiene el derecho a descontinuar su participación en cualquier momento. Si hubiera nuevos descubrimientos durante la investigación que pudieran afectar su voluntad de participar, se lo harán saber tan pronto sea posible.

Pudiera ocurrir que el investigador decidiera descontinuar su participación sin su consentimiento, porque piense que continuar en el estudio pudiera ser perjudicial para usted o porque nuestro beneficiario decida parar el estudio.

Firmar esta forma de consentimiento indica que usted ha leído esta forma (o se la han leído), que sus preguntas han sido contestadas a su satisfacción y que usted voluntariamente accede a participar en este estudio de investigación. Usted recibirá una copia firmada de esta forma de consentimiento.

_____|_____ _____
Firma del Participante y Nombre con Letra de Molde Fecha

_____|_____ _____
Representante legal autorizado (LAR) firma y nombre con Letra de Molde Fecha

_____|_____ _____
Firma de la Persona que Obtiene el Consentimiento y Nombre Fecha

FORMA DE CONSENTIMIENTO PARA INVESTIGACION

Consentimiento para crear una línea de células de su muestra de sangre

ESTUDIO DEL CORAZON DE FRAMINGHAM N01-HC-25195 1910G

Antecedentes

Una línea de células es una muestra congelada de células blancas de su sangre, que han sido especialmente procesadas para que el Estudio del Corazón de Framingham pueda reproducir más células blancas y así obtener más ADN, según se vaya necesitando para futuros estudios.

Propósito

Una línea de células será creada de una muestra de sangre que usted nos dé, para estudiar las causas de enfermedades del corazón y otras condiciones de salud, cómo prevenirlas y la posibilidad de estudiar la influencia de los factores genéticos para la salud.

Que Sucede en este Estudio de Investigación

Usted será una de las aproximadamente 1080 personas a quienes se les pedirá que participen en este estudio. Todo o parte del estudio se realizará en El Centro Médico de la Universidad de Boston (Boston University Medical Center o BUMC por sus siglas en Inglés).
La muestra de su sangre será tomada en el Estudio del Corazón de Framingham, localizado en 73 Mt. Wayte Ave. en Framingham, MA, o en su lugar de residencia. Un técnico tomará una muestra de su sangre (16 cc o alrededor de 1 cucharada) para la preparación de ADN (material genético) y para la creación de una muestra de células blancas vivas (línea de células).
Los riesgos de dar la muestra de sangre incluyen un pequeño moretón, dolor o sangrado. También puede ocurrir una alergia al látex. Si sabe que es alérgico al latex, por favor dígaselo al técnico para que use otro tipo de protección.

Riesgos y molestias

Pudiera haber riesgos y molestias hasta ahora desconocidos. Los empleados del estudio le actualizarán sobre cualquier información nueva que pudiera afectar su salud, su bienestar y su decisión de seguir participando en el estudio.

Posibles Beneficios

Usted no recibirá ningún beneficio directo de su participación en este estudio. Sin embargo, su participación puede ayudar a los investigadores a comprender mejor las causas y prevención de enfermedades cardiovasculares y otras condiciones de la salud, incluyendo la posibilidad de saber cómo los factores genéticos influencian el estado de salud.

Alternativas

Tiene la alternativa de no participar en el estudio.

Costos y pagos

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No se le cobrará por este examen. Si en su examen se descubriera algún problema médico que requiera más diagnóstico o tratamiento, se le avisará a usted y a su doctor o a la clínica que usted nos indique.

En caso de que su doctor decida que usted debe someterse a más exámenes clínicos o más tratamientos, estos deberán ser pagados ya sea por usted o por una tercera persona (por ejemplo su seguro médico o Medicare). No se harán arreglos especiales por compensaciones o pagos de tratamientos por el solo hecho de haber participado en este estudio. Este párrafo no cancela sus derechos legales.

Los gastos que puede incurrir el día de su participación incluyen (pero no se limitan) a costos de transportación (gasolina, peaje, etc.). A usted no se le pagará por participar en el estudio. Sin embargo, si fuera necesario, le proveeremos con transportación a la clínica y de vuelta a su hogar sin costo para usted.

Confidencialidad

La información obtenida durante el estudio será tratada con estricta confidencialidad. Se le asignará un código a usted y a cualquier información personal que pudiera identificarle. Las líneas de células serán guardadas en un lugar central. Los documentos que vinculen los nombres con las muestras serán guardados bajo llave y serán accesibles solo a los administradores de bancos de datos del Estudio del Corazón de Framingham. Las muestras con códigos serán guardadas hasta que ya no tengan valor científico. El riesgo en proveer esta muestra es mínimo.

La información de datos y el ADN será distribuido a los investigadores del Estudio del Corazón de Framingham y a investigadores calificados interesados en la genética de enfermedades del corazón y las venas, enfermedades del pulmón y la sangre, accidentes cerebro-vasculares, pérdida de memoria, enfermedades de las articulaciones, pérdida de densidad ósea, sordera, cáncer, y otras enfermedades graves y condiciones de salud. A los investigadores se les dará el ADN sin ningún dato que pudiera identificar a los donadores. La información obtenida de su ADN puede ser utilizada para el desarrollo de procedimientos para diagnosticar o para nuevos tratamientos de enfermedades graves. Su ADN no será vendido a ninguna persona, institución o compañía por ganancia financiera ni por beneficio comercial. Sin embargo, ni usted ni sus familiares ganarán provecho financiero de los descubrimientos hechos usando la información o especímenes que usted nos dé.

Cuando los resultados sean publicados, su nombre y cualquier otra información que lo pudiera identificar, no serán revelados. Se le mantendrá informado a través de publicaciones periódicas del Estudio del Corazón de Framingham sobre descubrimientos de genética, enfermedades cardiovasculares y otras condiciones de salud que hayan sido generadas de los análisis del ADN.

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Consentimiento para crear una línea de células de su muestra de sangre

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Para ayudarnos a proteger su privacidad, los investigadores calificados han obtenido un Certificado de Confidencialidad del Departamento de Salud y Derechos Humanos (DHHS). Con este certificado, los investigadores no pueden ser forzados (por ejemplo por la corte) a divulgar ninguna información que le pueda identificar en ningún procedimiento federal, estatal, local civil, criminal, administrativo, legislativo o ningún otro procedimiento. Sin embargo, el suministro de información será necesario si fuera requerido para una auditoría o evaluación del programa por parte del Departamento de Salud y Derechos Humanos. Por favor comprenda que un Certificado de Confidencialidad no lo previene a usted ni a su familia de voluntariamente suministrar información de usted mismo, ni de su participación en este estudio. Por ejemplo, si un asegurador o empleador sabe que usted es participante de este Estudio, y obtiene el consentimiento de usted mismo para obtener más información, en ese caso el investigador no podrá usar su Certificado de Confidencialidad para no divulgar su información. Esto significa que usted y su familia también deben actuar para proteger su propia privacidad. Finalmente, por favor comprenda que el investigador no está prevenido de tomar las medidas necesarias (incluyendo reportar a autoridades) para prevenir daños severos a usted mismo y a otros.

Tiene la opción de retirar su muestra de sangre en el futuro, en cuyo caso la muestra será destruida. Si elije retirar sus muestras, deberá comunicarse con la encargada del laboratorio del Estudio del Corazón de Framingham al 508-935-3477.

El Estudio del Corazón de Framingham es un proyecto de investigación médica patrocinado por los Institutos Nacionales de la Salud. Autorizado bajo 42USC285b-3. El sistema de registros aplicado al Estudio del Corazón de Framingham, está documentado en el Registro Federal: Septiembre 26, 2002 (Vol. 67, No. 1879) páginas 60776-60780.

Por favor cheque en la casilla apropiada si está o no está de acuerdo con el siguiente estatuto:

1. |___| SI |___| NO (Office Code 1)

Estoy de acuerdo en permitir la formación de una línea de células hecha con mi sangre para proveer un suministro renovable de ADN. (Una línea de células es una muestra de células blancas de su sangre, congeladas y procesadas, para poder reproducir más células blancas y así obtener más ADN para futuros estudios).

Derechos del Participante

Al darnos su consentimiento para participar en este estudio, usted no renuncia a ninguno de sus derechos legales. Dar consentimiento significa que usted ha escuchado o leído la información sobre este estudio y que está de acuerdo en participar. Se le dará una copia de

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esta forma.

Si en cualquier momento decidiera no seguir participando en este estudio, no sufrirá ningún tipo de penalidad ni perderá ningún beneficio al que tuviera derecho.

Puede obtener más información sobre sus derechos como sujeto en el estudio llamando a la Oficina de Revisión Institucional del Comité de Protección de Derechos Humanos del Centro Médico de la Universidad de Boston al 617-638-7207.
El investigador o algún miembro del equipo de investigadores tratará de responder a todas sus preguntas. Si en cualquier momento tiene preguntas o dudas, o si necesita reportar alguna herida ocurrida durante su participación en esta investigación, por favor comuníquese con el DR. PHILIP A. WOLF, o con el DR. DANIEL LEVY, al (508) 872-6562.

Compensación por daños relacionados con la Investigación

Si piensa que ha sido herido por participar en este estudio, por favor déjeselo saber al investigador inmediatamente. Si su participación es en el Centro Médico de Boston, puede obtener tratamiento por la herida en el Centro Médico de Boston. Si su participación NO es en el Centro Médico de Boston, pregúntele a su investigador dónde puede obtener tratamiento localmente para la herida. Usted y su seguro médico recibirán la cuenta por el tratamiento recibido. Algunos patrocinadores de investigación ofrecen un programa para cubrir parte de los costos del tratamiento que no son cubiertos por su seguro médico. Debería preguntarle al equipo de investigación si tal programa está disponible.

Sus Derechos a Rehusar o Descontinuar

Su participación en este estudio es voluntaria. Tiene el derecho de rehusar tomar parte en el estudio. Si decide participar y después cambia de opinión, puede salirse del estudio. Su participación es totalmente opcional. Su decisión no afectará el cuidado médico que pueda recibir en esta institución ni el pago de su cuidado médico. No afectará su inscripción a seguros médicos o beneficios que pudiera obtener.

Si decide tomar parte, tiene el derecho a descontinuar su participación en cualquier momento. Si hubiera nuevos descubrimientos durante la investigación que pudieran afectar su voluntad de participar, se lo harán saber lo más pronto posible.

Es posible que el investigador decida descontinuar su participación sin su permiso, porque pudiera decidir que continuar en el estudio será malo para usted o porque nuestro patrocinador interrumpa el estudio.

Firmar esta forma de consentimiento indica que usted ha leído esta forma (o se la han leído), que sus preguntas han sido contestadas a su satisfacción y que usted voluntariamente accede a participar en este estudio de investigación. Usted recibirá una copia de esta forma de consentimiento firmada.

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Firma del Participante y Nombre con Letra de Molde Fecha

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Representante legal autorizado (LAR) firma y nombre con Letra de Molde Fecha

_____|_____ _____

Firma de la Persona que Obtiene el Consentimiento y Nombre Fecha

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