BOSTON UNIVERSITY SCHOOLS OF MEDICINE, PUBLIC HEALTH, DENTAL MEDICINE AND THE BOSTON MEDICAL CENTER

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.

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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.

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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.*

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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.

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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.

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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, 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.

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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 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.

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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

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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.

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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**

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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 1 Cohort. This ninth examination of the FHS Omni 1 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,

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.

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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.

11) Follow Up: You may be contacted later by mail or by phone to obtain additional health information

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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.

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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.

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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.

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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

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Patenting Discoveries

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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)

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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.

Subject's Rights

By consenting to participate in this study you do not waive any of your legal rights. Giving consent

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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.

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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

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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.

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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**

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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.

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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.

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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