# Framingham Heart Study

Generation 3, NOS, Omni 2

EXAM 3

### Research Center Questionnaire

#### **SECTIONS:**

Admit (pages 1 - 6) plus consents

MD (pages 7 - 112)

Self-Administered Questions (pages 113 – 142)

Tech (pages 143 – 174)

Tonometry (pages 175 – 177)

**Admit Section** 



### Framingham Heart Study

A Project of the National Heart, Lung, and Blood Institute and Boston University

### **Participant Information**

Date of this FHS exam (today's date) * must provide value	Today M-D-Y
Site * must provide value	<ul><li>Heart Study</li><li>Nursing home</li><li>Residence</li><li>Other</li></ul>
First name	
Last name	
Date of Birth	Today M-D-Y

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Additional Comments		
Participant Information		
Imported Validated D	ata for Data Management Use	
imported validated b	ata for Data Management Use	
Year of birth	View equation	
Year of this FHS exam	View equation	
Age (in years)	View equation	
	© 2	
	© 3	
IDTYPE	© 72	
	2 = NOS, 3 = Gen 3,	
	3 = Gen 3, 72 = Omni Gen 2	
ID		
	FHS ID (4-digit)	
0	Male	
Sex	Female	
Date of last exam	Today M-D-Y	
Year of last exam	View equation	
Date of last medical health update	Today M-D-Y	
Date of last medical information	Today M-D-Y	



### Framingham Heart Study

A Project of the National Heart, Lung, and Blood Institute and Boston University

#### A02 - Research Proxy

I, living at:			
appoint the following person(s) to make decisions about my participation in the Framingham Heart Study ("Research Proxy"):			
Research Proxy Name:			
Relation:			
Address:			
City State Zip:			
Home Phone:			
Work Phone:			
Other Phone:			

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	e, I name this person (Optional):		
Alternate Proxy Name:			
Relation:			
Address:			
City State Zip:			
Home Phone:			
Work Phone:			
Other Phone:			
Effective Date and Termination  This durable power of attorney shall take effect when signed by me and shall not be affected by lapse in time or by my subsequent disability or incapacity which makes me unable to make decisions about participation in research.			
My Research Proxy shall have the authority to make all research participation decisions for me, including decisions about whether or not to enroll me or continue my participation in a research study [both minimal and greater than minimal risk research procedures as determined by the federal regulations and in consultation with the IRB]. My Research Proxy is to have the same authority to make research participation decisions as I would have. S/he has the authority to provide medical information and to consent for testing and examinations,. S/he further has the power to authorize the provision of records related to payment, treatment or services to me or on my behalf from any hospital, physician, or medical source to the Framingham Heart Study.			
authority to provide medical information and to consent for to authorize the provision of records related to payment, treatme physician, or medical source to the Framingham Heart Study.	esting and examinations,. S/he further has the pent or services to me or on my behalf from any l	ower to hospital,	
authority to provide medical information and to consent for to authorize the provision of records related to payment, treatm	esting and examinations,. S/he further has the pent or services to me or on my behalf from any l	ower to hospital,	
authority to provide medical information and to consent for to authorize the provision of records related to payment, treatme physician, or medical source to the Framingham Heart Study.	esting and examinations,. S/he further has the pent or services to me or on my behalf from any lare that I understand its contents and that I sign	ower to hospital,	
authority to provide medical information and to consent for to authorize the provision of records related to payment, treatm physician, or medical source to the Framingham Heart Study.  I, the undersigned Principal, by signing my name to this declared.	esting and examinations,. S/he further has the pent or services to me or on my behalf from any lare that I understand its contents and that I sign	ower to hospital, n it willingly.	
authority to provide medical information and to consent for to authorize the provision of records related to payment, treatm physician, or medical source to the Framingham Heart Study.  I, the undersigned Principal, by signing my name to this declar Principal:	esting and examinations,. S/he further has the pent or services to me or on my behalf from any lare that I understand its contents and that I sign  Today  M-D-Y  e of signing:]	nower to hospital, it willingly.	
authority to provide medical information and to consent for to authorize the provision of records related to payment, treatme physician, or medical source to the Framingham Heart Study. I, the undersigned Principal, by signing my name to this decimal principal:  Principal Date:  [Complete the following if the Principal is physically incapable in hereby sign the name of the Principal at the Principal's directions.]	esting and examinations,. S/he further has the pent or services to me or on my behalf from any lare that I understand its contents and that I sign  Today  M-D-Y  e of signing:]	nower to hospital, it willingly.	
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authority to provide medical information and to consent for to authorize the provision of records related to payment, treatme physician, or medical source to the Framingham Heart Study.  I, the undersigned Principal, by signing my name to this decidence.  Principal:  Principal Date:  [Complete the following if the Principal is physically incapable I hereby sign the name of the Principal at the Principal's direct witnesses.  Name of Signer:  Signer Date:	esting and examinations,. S/he further has the pent or services to me or on my behalf from any lare that I understand its contents and that I sign  Today M-D-Y  Te of signing:]  ction and in the presence of the Principal and tw	nower to hospital, it willingly.	

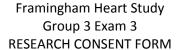
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#### Welcome Back to the Framingham Heart Study

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:

- 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.



FHS Group 3 (Generation 3, Omni 2, New Offspring Spouse Cohorts) Exam 3 Res. v17



#### 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. <u>Cardiopulmonary Fitness Evaluation</u>: 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.

<u>What risks can I expect?</u> 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. <u>Desktop AGE Reader (Skin Test)</u>: 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. <u>Fibroscan</u>: 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.





<u>What risks can I expect?</u> 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. <u>Electronic FHS (eFHS) Study</u>: 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.

<u>What risks can I expect?</u> 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. <u>Accelerometer:</u> 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.

<u>General Risks:</u> 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.

<u>Unknown Risks</u>: 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	I	Date
Person Obtaining Consent Signature	Printed Name		Date



Exam Form Version Date: 12-13-2017





#### RESEARCH CONSENT FORM

Blood Draw Consent for Cell Line Creation
THE FRAMINGHAM HEART STUDY NO1-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.

Blood Draw Consent for Cell Line Creation Res.y10

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





#### RESEARCH CONSENT FORM

Blood Draw Consent for Cell Line Creation
THE FRAMINGHAM HEART STUDY NO1-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.

Blood Draw Consent for Cell Line Creation Res.y10

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





#### RESEARCH CONSENT FORM

### Blood Draw Consent for Cell Line Creation THE FRAMINGHAM HEART STUDY NO1-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.

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#### 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.

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#### **RESEARCH CONSENT FORM**

Blood Draw Consent for Cell Line Creation
THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

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 signe 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

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Exam Form Version Date: 12-13-2017





## Forma de Consentimiento de Investigación para el Grupo 3 Examen 3 del Estudio del Corazón de Framingham

#### Bienvenido de Nuevo al Estudio del Corazón de Framingham

Juntos estamos ayudando a combatir enfermedades del corazón y otras importantes enfermedades y condiciones de salud a través de la investigación médica.

#### ¿Por qué se está haciendo este estudio de investigación?

El Estudio del Corazón de Framingham (Framingham Heart Study o FHS, por sus siglas en inglés) es un estudio de investigación a largo plazo. El propósito del estudio es:

- (1) Ayudar a comprender cómo se desarrollan enfermedades de corazón y los vasos sanguíneos, enfermedades del pulmón y la sangre, derrames cerebrales, pérdida de memoria, cáncer y otras enfermedades y condiciones de salud importantes; y
- (2) Examinar el ADN y su relación con los riesgos a desarrollar estas enfermedades y otras condiciones de salud.

El examen que se llevará a cabo como parte de este estudio de investigación no es lo mismo que cuidados médicos en una clínica. Las pruebas son sólo con fines de investigación. No ofrecemos servicios médicos. Este examen no reemplaza su chequeo regular con su médico de cabecera.

#### Acerca de su consentimiento

Por favor lea cuidadosamente este formulario de consentimiento de investigación. Le da importante información sobre el estudio. Tomar parte en un estudio de investigación es voluntario. La decisión de participar o no, en todo o en parte del examen depende totalmente de usted. Si usted decide participar, puede decidir dejar de hacerlo en cualquier momento. Su decisión será honrada y respetada. No habrá ninguna multa si usted decide dejar de participar.

### ¿A quién puedo llamar si tengo preguntas o dudas acerca de este estudio de investigación?

Si tiene alguna pregunta acerca de este estudio o este formulario, por favor déjenos saberlo. Puede llamarnos con sus preguntas o dudas las veces que quiera.

Puede llamar al personal del estudio en inglés al (508) 872-6562, o en español al (508) 935-3485 o puede enviar un correo electrónico a FHS@bu.edu.

El Estudio del Corazón de Framingham se lleva a cabo por los investigadores de la Universidad de Boston, el Instituto Nacional Cardiaco, Pulmonar y Sanguíneo, y el Instituto Nacional de la Salud. El Dr. Vasan S Ramachandran y el Dr. Daniel Levy están a cargo de la investigación. Puede contactar al Dr. Ramachandran al (617) 638-8090 de lunes a viernes entre 9:00 y 17:00 o por correo electrónico a <a href="mailto:vasan@bu.edu">vasan@bu.edu</a> y al Dr. Levy al (508) 935-3400 de lunes a viernes entre 9:00 y 17:00 o por correo electrónico a levyd@nih.gov.

Si desea hablar con alguien que no esté directamente involucrado en este estudio de investigación, por favor póngase en contacto con la Junta de Revisión Institucional del Centro Médico de la Universidad de Boston (BUMC) al (617) 638-7207.





## Forma de Consentimiento de Investigación para el Grupo 3 Examen 3 del Estudio del Corazón de Framingham

#### ¿Qué pasará en este examen de investigación?

Usted necesitará ayunar por 12 horas antes de llegar a su cita debido a la muestra de sangre que tomaremos. Si toma medicinas en la mañana, hágalo como siempre y asegúrese de tomar agua en la mañana de su visita.

Su examen se llevará a cabo en el Centro de Investigación del Estudio del Corazón de Framingham (FHS) en 73 Mount Wayte Avenue, Framingham, MA, o en su hogar u otra residencia. El examen aquí tomará alrededor de 4 horas.

#### Como en los exámenes anteriores,

- Tomaremos una muestra de sangre para pruebas genéticas y de laboratorio, para poder comprender mejor los factores de riesgo de enfermedades del corazón y otras enfermedades bajo estudio (por ejemplo, la cantidad y función de diferentes tipos de colesterol en la sangre). La cantidad total de sangre extraída será alrededor de 120 ml, que son unas 8 cucharadas. La toma de sangre se producirá en dos etapas: la primera poco después de su llegada y la segunda después de la evaluación cardio-pulmonar de su condición física.
- · Colectaremos una muestra de orina
- Mediremos su peso y altura
- Realizaremos un electrocardiograma (ECG)
- Mediremos su presión arterial
- Actualizaremos su historial clínico
- Haremos una prueba de función vascular para medir la rigidez de los vasos sanguíneos (arterias) mediante el registro de ondas producidas mientras se mide la presión arterial
- Le pediremos que firme un formulario de consentimiento para que nos dé permiso de obtener expedientes médicos incluyendo de Medicare. Este formulario será válido hasta que usted lo cancele
- Le contactaremos más adelante por correo, email o por teléfono, para obtener información adicional o para invitarlo a participar en otros estudios relacionados con FHS. También puede ser invitado a participar de nuevo a otro de nuestros exámenes.

#### **Encuestas**

También le pediremos que llene unos cuestionarios sobre su función física, dieta, ejercicio, memoria, estado de ánimo y hábitos de vida, incluyendo si fuma o consume alcohol. Algunos de los cuestionarios ya los ha hecho, otros serán nuevos para usted.

Algunas de sus respuestas se grabarán mediante una grabadora audio-digital. Las grabaciones serán analizadas junto con otra información del estudio. También usaremos las grabaciones para asegurarnos que sus respuestas estén documentadas correctamente.





## Forma de Consentimiento de Investigación para el Grupo 3 Examen 3 del Estudio del Corazón de Framingham

#### Hay algunas nuevas actividades de investigación.

1. Evaluación del estado cardio-pulmonar: La evaluación de su condición cardio-pulmonar está diseñada para averiguar la eficacia de su corazón, los pulmones y la circulación de la sangre. Le pediremos que haga ejercicio en una bicicleta estacionaria mientras usted esté conectado a máquinas que graban su respiración y función cardiaca. Le pediremos que pedalee tanto como pueda. Mientras pedalea, la respiración se efectuará en un tubo que medirá el aire que inhala y exhala. Se observarán su ritmo cardíaco y la presión arterial a lo largo de esta actividad. Vigilaremos su ritmo cardíaco mediante un electrocardiograma (ECG) colocando pequeños adhesivos a la piel. Esta prueba tomará unos 30 minutos en total, de los cuales 10 a 15 minutos serán haciendo ejercicio. Al final de esta prueba, tomaremos una muestra de sangre de alrededor de 25 ml o 2 cucharadas.

¿Qué riesgos puedo esperar? Como con cualquier ejercicio moderado, puede cansarse y tener dificultad para respirar; esto es normal. Es probable que aumente la frecuencia cardíaca y presión arterial. En raras ocasiones, pueden ocurrir cambios anormales tales como desmayo, latidos cardíacos irregulares y baja presión arterial. En muy raras ocasiones pudiera ocurrir un ataque cardíaco, como con cualquier otra actividad extenuante. Se hará todo lo posible para reducir al mínimo cualquier posible riesgo vigilándolo constantemente durante la prueba así como pudiendo detener las pruebas en cualquier momento. Equipo especial y nuestro personal capacitado estarán disponibles para hacer frente a situaciones inusuales, si ocurrieran.

Como resultado de la toma de sangre, pudieran surgir moretones, dolor o sangrado, o en muy raras ocasiones infección. También, aunque raro, algunas personas pueden sentirse mareadas o débiles.

- 2. Estudio del hueso: Tomografía computarizada de alta resolución periférica cuantitativa del hueso del antebrazo y la pierna: estando sentado, se coloca el antebrazo sobre un soporte y se coloca dentro de la máquina para tomar el examen. Después haremos lo mismo con su pierna. Es importante que se mantenga lo más quieto posible durante este escaneo.
  - Exploración de absorciometría de rayos x de energía dual de la cadera y todo el cuerpo: esta prueba implica recostarse en una mesa acolchada. La máquina de escaneo pasará sobre su cadera y todo su cuerpo.

¿Qué riesgos puedo esperar? Las pruebas de densidad ósea implican el uso de rayos x, que son una forma de radiación. Sin embargo, la radiación a la que estará expuesto como parte de este estudio es tan pequeña que no hay ningún riesgo significativo para la salud.



## Forma de Consentimiento de Investigación para el Grupo 3 Examen 3 del Estudio del Corazón de Framingham

Debido al riesgo potencial para un feto, las mujeres que estén embarazadas, ya sea porque lo hayan reportado directamente o porque en nuestra prueba de embarazo hayan salido positivas, serán excluidas de este examen del hueso.

- 3. Medidor de edad (prueba cutánea): Esta prueba mide la cantidad de un tipo especial de colágeno en la piel de su antebrazo que puede ser afectado por los niveles de azúcar en la sangre. La cantidad de este tipo especial de colágeno en la piel se relaciona con la cantidad en el hueso. Limpiaremos el brazo con un trapo mojado. Luego colocaremos su antebrazo en el aparato de escaneo y una luz brillará sobre su piel para realizar la medición.
  - ¿Qué riesgos puedo esperar? No existen riesgos conocidos asociados con este escaneo de la piel.
- 4. <u>F</u>ibroScan: El fibroscan es un examen para medir la presencia de grasa o cicatrices en el hígado. Se genera un pulso sin dolor que viaja al hígado y mide su dureza.
  - ¿Qué riesgos puedo esperar? Puede haber pequeñas molestias por la aplicación del gel y la presión sobre la piel con la punta del aparato fibroscan. Sin embargo no hay riesgos conocidos asociados con el fibroscan.
  - Hay algunas condiciones que pueden interferir con la capacidad del dispositivo para obtener medidas válidas. Estas incluyen: estar embarazada, tener líquido en la cavidad abdominal (ascitis) y tener implantes médicos, como un marcapasos. Le preguntaremos sobre esto, pero por favor, háganos saber si tiene alguna de estas condiciones para no realizar el fibroscan.
- 5. Petición adicional para pedir registros médicos a Madicare usando su número de seguro social: Se le preguntará si investigadores del estudio, así como colaboradores de otros institutos, incluyendo la Universidad de Duke, pueden relacionar su número de seguro social con la base de datos de Medicare y Medicaid para obtener información de Medicare. Los número de seguro social no serán compartidos con ninguna institución no relacionada con el Estudio del Corazón de Framingham, excepto con su consentimiento o como lo requiera la ley.
  - ¿Que riesgos puedo esperar? Hacemos nuestro mejor esfuerzo para proteger su información del estudio (véase abajo). Sin embargo aún existe el riesgo de pérdida de confidencialidad.





Forma de Consentimiento de Investigación para el Grupo 3 Examen 3 del Estudio del Corazón de Framingham

#### Pruebas para llevar a casa:

6. Estudio electrónico del FHS (eFHS): Si vive en los Estados Unidos, tiene correo electrónico y acceso diario a internet o un iPhone, le invitamos a participar en el estudio eFHS. Tomar parte requiere que descargue aplicaciones y use dispositivos inalámbricos. Las aplicaciones requieren completar encuestas sobre salud y estilo de vida. Los dispositivos electrónicos miden la frecuencia cardíaca, presión arterial, peso y actividad física.

¿Qué riesgos puedo esperar? No existen riesgos conocidos por participar en este estudio.

- 7. Colección fecal: Le preguntaremos si desea realizar otro estudio en casa, para enviar sus heces por correo a un laboratorio. El propósito de este estudio es entender mejor las causas de enfermedades cardiovasculares y diabetes mediante el estudio de las bacterias que están presentes en el intestino y las funciones biológicas que éstas realizan. El kit casero contiene instrucciones y todo lo necesario para la colección de materia fecal, así como una hoja con preguntas sobre cómo se ha sentido recientemente, los alimentos que haya estado comiendo recientemente y el aspecto de las heces.
  - ¿Qué riesgos puedo esperar? Colectar heces pudiera hacerlo sentir incómodo. Así como responder a algunas preguntas del cuestionario del kit de colección de heces. Usted puede elegir no contestar las preguntas que no quiera responder. Sus respuestas se mantendrán confidenciales y no se asociarán a su nombre ni a su información de identificación personal.
- 8. <u>Acelerómetro:</u> Se le preguntará si quiere usar un monitor de actividad física por una semana. Se pone en un cinturón y se envía de vuelta al FHS. Mide qué tan activo está usted durante el día.

¿Qué riesgos puedo esperar? No existen riesgos conocidos por participar en este estudio.

Riesgos Generales: Este estudio lleva tiempo y es repetitivo. Otras molestias incluyen dolor de cabeza, el sentirse con hambre o frío y tener fatiga mientras está aquí. No esperamos ningún riesgo a que se lesione como resultado de su participación en el estudio. Sin embargo, tenemos disponibles primeros auxilios.

<u>Riesgos D</u>esconocidos: Existe la posibilidad de otros riesgos que no hemos identificado hasta el momento.





## Forma de Consentimiento de Investigación para el Grupo 3 Examen 3 del Estudio del Corazón de Framingham

#### Estudios genéticos

Planeamos hacer investigaciones genéticas con el ADN de sus muestras biológicas, las cuales incluyen células sanguíneas, células de los tejidos, heces, etc. El ADN es el material de lo que están hechos sus genes. Los genes pasan del padre y la madre al niño. Todos los seres vivos están compuestos de células. Los genes son la parte de las células que contienen las instrucciones para decirle a nuestro cuerpo cómo crecer y trabajar, y determinar sus características físicas; como cabello y color de ojos.

También, si está de acuerdo, en un laboratorio procesaremos las células blancas de la sangre de una de sus muestras para convertirlas en células madre. Las células resultantes son conocidas como células madre con pluripotencialidad inducida (células iPS), y se utilizan en el laboratorio para que actúen como células de otros órganos; tales como células del hígado, células grasas, células del corazón, células pulmonares, vasculares, intestinales, células nerviosas, diferentes tipos de células sanguíneas y muchos otros tipos de células naturales. Estas células y los productos celulares que pueden obtenerse de ellas; tales como RNA, proteínas y metabolitos, pueden ser estudiados en laboratorios para aprender más sobre las causas de la salud o enfermedad de éstos órganos.

Las células serán guardadas indefinidamente en un repositorio de células madre en la Universidad de Boston. Las células también pueden almacenarse en un repositorio central o banco.

Si está de acuerdo, sus tejidos, células o cualquier línea de células iPS o sus derivados, podrían ser usados en el futuro para estudios relacionados y no-relacionados como:

- Inyección o trasplante de células madre o sus derivados a animales para fines de investigación. Sus muestras podrían ser usadas en estudios que involucran manipulación genética pero jamás serán usadas para clonar o reproducir a un ser humano completo.
- Pruebas genéticas y composición del ADN. Los genes pueden ser analizados o manipulados para estudiar su función normal y desarrollo. El ADN de algunas células madre o sus derivados, podría ser alterado.
- Otros usos que implican investigación o desarrollo de productos comerciales para el diagnóstico, prevención o tratamiento de diversas enfermedades.
- Muestras obtenidas de usted en este estudio (células sanguíneas, células iPS o sus derivados) pueden ser utilizadas en el desarrollo de uno o más productos terapéuticos o de diagnóstico que podrían ser patentadas y autorizadas por los investigadores involucrados en la investigación o en el desarrollo de estos productos. No hay planes para proporcionar compensación económica si esto ocurriera.





## Forma de Consentimiento de Investigación para el Grupo 3 Examen 3 del Estudio del Corazón de Framingham

#### ¿Cómo puedo saber los resultados de este estudio?

La principal manera en que los resultados de este estudio son reportados, es a través de publicaciones científicas y con presentaciones en reuniones científicas. En nuestros boletines anuales a veces describimos resúmenes de los resultados.

También informaremos los resultados de mediciones rutinarias de investigación a usted o su proveedor de atención médica en el momento del examen o después de su visita. Estos pueden incluir por ejemplo, la presión arterial y el colesterol.

En algunos casos, si determinamos que es apropiado, podemos reportarle a usted y/o a su proveedor de atención médica los hallazgos de investigación que se relacionen con usted, si nos da su permiso. Esta información, si se da a conocer, podría tomar mucho tiempo después de su visita por una serie de razones: por ejemplo, podría llevar años de trabajo para analizar la información y llegar a resultados de investigación, quizás utilizando métodos científicos que han sido desarrollados solo recientemente.

Nuestra investigación genética podría generar resultados que sean relevantes para usted y posiblemente su familia; tales como información sobre una variante genética particular que lo pudiera poner en riesgo de una condición de salud grave. Por el momento, pensamos que la mayoría de los hallazgos de investigación genética no tienen gran importancia médica para las personas, pero el campo de la genética está cambiando rápidamente.

Actualmente no tenemos planes concretos de contactarlo a usted o a su proveedor de salud sobre los resultados de las diferentes investigaciones genéticas o no-genéticas excepto por las mediciones de pruebas rutinarias de la investigación. En general, no nos podemos comprometer a proporcionarle otros resultados del estudio. En cuanto a determinar si compartimos información adicional de la investigación con usted, tendremos en cuenta una serie de consideraciones según cada caso en particular. Estos pueden incluir si los hallazgos se basaron en pruebas que son clínicamente aceptables, precisas y fiables, si los resultados revelan un riesgo significativo de una condición de salud grave, si existe en el momento pertinente un tratamiento reconocido o la intervención de prevención u otras acciones disponibles que tienen el potencial para cambiar el curso clínico de la condición de salud, si informar o no informar los resultados pudiera aumentar el riesgo de daño a usted, y otros factores relevantes que quizá no seamos capaces de predecir en este momento.

Las mediciones y resultados de una investigación científica no equivalen a los resultados de pruebas clínicas. Como tal, nuestro examen de investigación no se realiza necesariamente por personas calificadas con formación clínica, y muchas partes de la examinación no cumplen con las normas requeridas para pruebas clínicas certificadas. Por esta razón, nuestras pruebas de investigación no son confiables para hacer diagnósticos, tratamientos ni decisiones para planes de salud. No proporcionar una atención de salud o dar consejos médicos o pruebas genéticas o





## Forma de Consentimiento de Investigación para el Grupo 3 Examen 3 del Estudio del Corazón de Framingham

brindar asesoramiento. Si usted o su proveedor de atención médica decide hacer pruebas adicionales de seguimiento o los tratamientos necesarios, usted (o un tercero, como un seguro de salud o Medicare) será responsable por esos costos.

#### ¿Cómo son compartidas mis muestras y mi información con otros investigadores?

Las muestras e información serán guardadas indefinidamente. Si está de acuerdo, su datos y sangre donada, células de sangre, células iPS o sus derivados, orina y otros especímenes pueden ser compartidos con otros investigadores; incluyendo otras entidades académicas con o sin fines de lucro, como hospitales, universidades, bancos de almacenamiento de células/tejidos y repositorios, bases de datos y repositorios de datos y empresas (ya sea con fines relacionados o no con estudios de investigación). Ninguna muestra o información será etiquetada con su nombre o ningún otro identificador personal. Solo con códigos.

Información de grabaciones de audio codificadas, será analizada por colaboradores calificados dentro y fuera de BUMC. Su nombre y otros identificadores personales directos, no se compartirán con estas entidades.

Usted tiene el derecho a negarse a permitir que sus datos y muestras sean usadas o compartidas para investigación adicional. Por favor marque la casilla apropiada en la lista de abajo.

Si usted da su permiso para que sus datos y muestras biológicas sean utilizadas o compartidas para investigación adicional, usted podrá retirar su autorización en cualquier momento poniéndose en contacto con los investigadores de FHS. Sin embargo, si sus datos o muestras ya han sido compartidas con otros investigadores, no seremos capaces de instruirles para dejar de usarlas o destruirlas, así como los productos hechos de estas muestras. Sus datos y muestras no incluirán su nombre ni otros identificadores directos.

#### ¿ Qué riesgos puedo esperar?

Participar en investigación genética podría tener un impacto negativo para usted, su familia y sus seres queridos. Los estudios genéticos podrían producir resultados en la investigación que se relacionen con riesgos a una condición de salud seria u otra información genética que podríamos considerar apropiado informarle a usted y su proveedor de atención médica, si es que lo desea (véase abajo). Esto podría presentarle con decisiones difíciles respecto a la información disponible y correr el riesgo de saber sobre enfermedades que usted y sus miembros familiares pudieran enfrentar. Saber los resultados de una investigación genética podría ocasionar ansiedad, e influir en decisiones relativas a matrimonio, planificación familiar y otros temas.

#### ¿Cómo está protegida mi información?

Tomamos medidas para cerciorarnos de que la información personal que recopilamos acerca de usted se mantenga privada y segura. Etiquetamos sus muestras e información con un código, y mantenemos las claves de los códigos en una base de datos protegida con





## Forma de Consentimiento de Investigación para el Grupo 3 Examen 3 del Estudio del Corazón de Framingham

contraseña. Sólo al personal autorizado se da la contraseña. Usamos otros medios seguros en nuestras instalaciones, sistemas y tecnología para proteger su seguridad y su información. *No vendemos, rentamos ni arrendamos su información de contacto.* 

Su nombre y otros identificadores personales directos no se usan cuando la información de este estudio es publicada o presentada en reuniones científicas, ni cuando sus muestras o información se comparten con otros investigadores, ni cuando las guardamos en repositorios y bancos de muestras y datos.

Sin embargo, no garantizamos la privacidad total. Nosotros podemos dar acceso a su información para realizar el estudio y para asegurarnos de que hacemos el estudio según las normas establecidas por la ética, el derecho y grupos de calidad. La información puede hacerse disponible a los investigadores que forman parte de este estudio, pero también a la Junta de Revisión Institucional que dirige esta investigación, a empleados y organizaciones que necesitan la información para hacer su trabajo en la realización y supervisión del estudio, personas o grupos que nos contratan para trabajar para nosotros (como empresas de almacenamiento de datos o "biosample", compañías de seguros y abogados) y organismos federales y estatales, según lo exija la ley o si están implicados en la investigación o supervisión de nuestro estudio. En la mayoría de los casos, cualquier información que se da es identificada con códigos y no con su nombre u otros identificadores personales directos. Una vez que se da información a terceros, no podemos prometer que será mantenida privada. Tenga en cuenta que su información personal puede darse si es requerida por la ley (como por ejemplo, para evitar posibles lesiones a usted o a otros).

Para ayudar a proteger su privacidad, los investigadores han obtenido un certificado de confidencialidad del Departamento de Salud y Servicios Humanos (DHHS). Con este certificado, los investigadores no pueden ser forzados (por ejemplo mediante citación del Tribunal) a revelar información que pueda identificarlo en ningún procedimiento legislativo civil, penal, administrativo, federal, estatal o local, ni en otros procedimientos del estudio. Sin embargo, sí se puede dar a petición del DHHS y para fines de auditoría o para evaluar el programa. Un certificado de confidencialidad no impide que usted o un miembro de su familia voluntariamente otorgue información sobre usted o su participación en este estudio. Si un asegurador o empleador se entera de su participación y obtiene su consentimiento para recibir información de la investigación, FHS no está permitido utilizar el certificado de confidencialidad para ocultar esta información. Esto significa que usted y su familia también deben proteger su propia privacidad. Por último, debe entender que el certificado de confidencialidad no impide a los investigadores tomar ciertas medidas, como informar a las autoridades, para evitar daños graves a usted o a otros.

#### Patente de Descubrimientos

Un día, la investigación de este estudio resultará en nuevas pruebas para diagnosticar o predecir enfermedades. También puede llevar al desarrollo de nuevas formas de prevenir o tratar enfermedades. Como es el caso de todas las investigaciones financiadas por el gobierno





## Forma de Consentimiento de Investigación para el Grupo 3 Examen 3 del Estudio del Corazón de Framingham

federal, los investigadores y sus empleadores son permitidos por la Ley Federal de Patentes de Descubrimientos, ganar financieramente. Ni usted ni sus herederos se beneficiarán financieramente.

#### ¿Cuáles son los posibles beneficios de mi participación en este estudio?

A usted no se le pagará por participar en el estudio ni obtendrá beneficios médicos como resultado de su participación. Sin embargo, esperamos que este estudio nos ayude a comprender mejor qué es lo que causa enfermedades del corazón y otras enfermedades y condiciones, así como las mejores maneras de prevenir y tratar estas enfermedades.

#### ¿Cuáles son mis costos por tomar parte en el estudio?

Los costos que pudiera incurrir el día de su participación incluyen, pero no están limitados a, costos de transporte (gasolina, peajes, etc) y el no poder trabajar el tiempo que esté aquí.

El Estudio del Corazón de Framingham no hará arreglos especiales de compensación o pago por su participación en este estudio. Si piensa que ha sufrido una lesión por estar en este estudio, por favor, dígaselo a los investigadores de inmediato. La Universidad de Boston y los patrocinadores del estudio, no ofrecen un programa de compensación debido al costo por la atención médica que pudiera recibir si sufriera lesiones, discapacidad, dolor, malestar u otros gastos, como pérdida de salario. Si sufriera lesiones aquí y si su seguro médico no cubriera su atención médica, no le compensaremos por el gasto de la atención médica que reciba. Esto no renuncia a ninguno de sus derechos legales.

#### ¿Cuánto tiempo estaré en el estudio?

El Estudio del Corazón de Framingham es un estudio a largo plazo.

Tomar parte en este estudio depende solo de usted. Si decide tomar parte hora, puede cambiar de parecer y dejar de participar en el futuro.

Le haremos saber si encontramos información nueva que pudiera hacerlo cambiar de parecer respecto a su participación en este estudio.

El investigador puede decidir suspender su participación sin su permiso, por el hecho de que él o ella pueda decidir que seguir en el estudio sería malo para usted, o porque nuestro patrocinador deje de dar fondos para el estudio.





# Forma de Consentimiento de Investigación para el Grupo 3 Examen 3 del Estudio del Corazón de Framingham

#### Por favor lea las siguientes afirmaciones y marque la casilla apropiada abajo:

1)	Estoy de acuerdo en participar en el examen del FHS, que incluye colección de datos, sangre, muestras de orina y varias pruebas de investigación y mediciones. Estoy de acuerdo en que se usen mis datos, muestras y materiales de investigación para los estudios de factores que contribuyen a enfermedades del corazón, los vasos sanguíneos, los pulmones y la sangre, movimiento, pérdida de memoria, cáncer y otras enfermedades y condiciones de salud.
	SI    NO (Office Code 0)
2)	Estoy de acuerdo en permitir que se hagan células con pluripotencialidad inducida (células iPS) de mi sangre y que sean alteradas para que funcionen como células de otros órganos.
	SI    NO (Office Code 13)
3)	Estoy de acuerdo en permitir que mis datos, sangre, ADN y otro material genético, células iPS y sus derivados, muestras de orina y otros especímenes sean utilizados en la investigación genética de factores que contribuyen a enfermedades del corazón y los vasos sanguíneos, pulmón y enfermedades de la sangre, accidentes cerebrovasculares pérdida de memoria, cáncer y otras enfermedades y condiciones de salud.
	SI    NO (Office Code 3)
4)	Estoy de acuerdo en permitir que investigadores de empresas comerciales tengan acceso a mis datos, sangre, ADN y otro material genético, células iPS y sus derivados, muestras de orina y otros especímenes para investigación. Entiendo que mis datos y muestras se compartirán sin mi nombre o identificadores personales directos.
	SI    NO (Office Code 4)
5)	Estoy de acuerdo en permitir que el FHS comparta conmigo, mi doctor, clínica, hospital u otro proveedor de salud, los resultados de los exámenes y las pruebas de investigación no-genéticas.
	SI    NO (Office Code 30)
6)	Estoy de acuerdo en permitir que el FHS me dé, y con mi permiso también a mi médico, clínica, hospital u otro proveedor de salud, información relativa a la investigación genética referente a mí.
	SI    NO (Office Code 31)

Res. v17



# Forma de Consentimiento de Investigación para el Grupo 3 Examen 3 del Estudio del Corazón de Framingham

Firmar este formulario de consentimiento indica que usted ha leído este formulario de consentimiento (o se lo han leído a usted), que sus preguntas han sido contestadas a su satisfacción, y que acepta voluntariamente a participar en este estudio de investigación. Usted recibirá una copia de este formulario de consentimiento firmado.

Firma del participante		Nombre con Letra de Molde	I	Fecha
Firma del representante legal autorizado (LAR)	I	Nombre con Letra de Molde	I	Fecha
Firma de la persona que obtiene el consentimiento		Nombre con Letra de Molde	Ι	Fecha

Res. v17



#### 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.

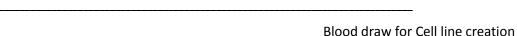
#### **Posibles Beneficios**

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



Res V 10





#### 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

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.

METEN.

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#### 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

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	I	SI	I NO	Office	Code '	1
	ı	OI	140		Coac	٠,

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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#### 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

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.

MENEN

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#### 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

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

Exam Form Version Date: 12-13-2017

# Framingham Heart Study

Generation 3, NOS, Omni 2

EXAM 3

### Research Center Questionnaire

#### **SECTIONS:**

Admit (pages 1 - 6) plus consents

MD (pages 7 - 112)

Self-Administered Questions (pages 113 – 142)

Tech (pages 143 – 174)

Tonometry (pages 175– 177)

**MD** Section



## Framingham Heart Study

A Project of the National Heart, Lung, and Blood Institute and Boston University

### **Medical Encounters**

1st Examiner ID		
Since you last provided medical information	n ([lastmedinfodate]) have you had any of the following?	
	No	
Hospitalizations (not E.R.)?	Yes	
,	Unknown	
If "Yes"		
Hospitalization #1		
Reason		
Year	2002-2021,	
	9999 = Unknown	

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DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	
Name of hospital	
Location of hospital	
Location of Hospital	City, State
	O No
Have you had another hospitalization?	<ul><li>Yes</li><li>Unknown</li></ul>
	GIINIOWII
Hospitalization #2	
Reason	
Year	2002-2021, 9999 = Unknown
DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	
Name of hospital	
Location of hospital	
	City, State
	O No
Have you had another hospitalization?	<ul><li>Yes</li><li>Unknown</li></ul>
	- Cilidiowii
Hospitalization #3	
Reason	
Voor	
Year	2002-2021, 9999 = Unknown
DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	
Name of hospital	
Location of hospital	
• *	City, State
	O No
Have you had another hospitalization?	<ul><li>Yes</li><li>Unknown</li></ul>

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Hos	spitalization #4		
	Reason		
	Year	2002-2021, 9999 = Unknown	
	DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)		
	Name of hospital		
	Location of hospital	City, State	
If pa	articipant has had more than 4 hospitalizations, p	provide details in "Additional Comments" below.	
E.R. visits	s only?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>	
If "Yes"			
E.R	. Visit #1		
	Reason		
	Year	2002-2021, 9999 = Unknown	
	DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)		
	Name of hospital		
	Location of hospital	City, State	
Have	e you had another E.R. visit?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>	
E.R	. Visit #2		
	Reason		
	Year	2002-2021, 9999 = Unknown	
	DATE details		

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Name of hospital	
Location of hospital	City, State
Have you had another E.R. visit?	No Yes Unknown
E.R. Visit #3	
Reason	
Year	2002-2021, 9999 = Unknown
DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	
Name of hospital	
Location of hospital	City, State
Have you had another E.R. visit?	No Yes Unknown
E.R. Visit #4	
Reason	
Year	2002-2021, 9999 = Unknown
DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	
Name of hospital	
Location of hospital	City, State
If participant has had more than 4 E.R. visits, provide o	letails in "Additional Comments" below.
Day surgery?	No Yes Unknown

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#### If "Yes"

Day	/ Surgery #1		
	Reason		
	Year	2002-2021, 9999 = Unknown	
	DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)		
	Name of hospital or doctor		
	Location of hospital or doctor	City, State	
Hav	e you had another day surgery?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>	
Day	/ Surgery #2		
	Reason		
	Year	2002-2021, 9999 = Unknown	
	DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)		
	Name of hospital or doctor		
	Location of hospital or doctor	City, State	
Hav	e you had another day surgery?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>	
Day	/ Surgery #3		
	Reason		
	Year	2002-2021, 9999 = Unknown	
	DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)		
	Name of hospital or doctor		

Location of hospital or doctor	City, State
Have you had another day surgery?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
Day Surgery #4	
Reason	
Year	2002-2021, 9999 = Unknown
DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	
Name of hospital or doctor	
Location of hospital or doctor	City, State
If participant has had more than 4 day surgeries, provi	ide details in "Additional Comments" below.
Major illness with visit to doctor?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
If "Yes"	
Major IIIness #1	
Reason	
Year	2002-2021, 9999 = Unknown
DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	
Name of doctor	
Location of doctor	City, State
Have you had another major illness with visit to doctor?	<ul><li>No</li><li>Yes</li></ul>

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Reason	
Year	
i <del>C</del> ai	2002-2021, 9999 = Unknown
	7777 - UTINTOWIT
DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	
Name of doctor	
Location of doctor	City, State
	City, State
	O No
ave you had another major illness with visit to	Yes
octor?	Unknown
Major IIIness #3	
Reason	
Year	2002-2021,
	9999 = Unknown
DATE details	
(e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	
Name of doctor	
Location of doctor	
	City, State
	No
lave you had another major illness with visit to	<ul><li>Yes</li></ul>
octor?	Unknown
lajor Illness #4	
Reason	
,	
•	
Year	2002-2021,
	9999 = Unknown
DATE details	

Location of doctor	City, State
If participant has had more than 4 major illnesses, pro	ovide details in "Additional Comments" below.
Checkup or office visit with doctor or other health care provider?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
If "Yes"	
Checkup or office visit #1	
Reason	
Year	2002-2021, 9999 = Unknown
DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	
Name of doctor	
Location of doctor	City, State
Have you had another checkup or office visit with doctor or other health care provider?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
Checkup or office visit #2	
Reason	
Year	2002-2021, 9999 = Unknown
DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	
Name of doctor	
Location of doctor	City, State
Have you had another checkup or office visit with doctor or other health care provider?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>

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Year	2002-2021, 9999 = Unknown
DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	
Name of doctor	
Location of doctor	City, State
Have you had another checkup or office visit with doctor or other health care provider?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
Checkup or office visit #4	
Reason	
Year	2002-2021, 9999 = Unknown
DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	
Name of doctor	
Location of doctor	City, State
If participant has had more than 4 checkups or office	e visits, provide details in "Additional Comments" below.
Additiona	al Comments
cal Encounters	

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# Framingham Heart Study

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### **Aspirin, Diagnoses and Treatment Questions**

Aspirin		
	No	
Do you take aspirin REGULARLY?	Yes	
	Unknown	
If "Yes"		
How many aspirin?		
, .	999=Unknown	
	Day	
	Week	
How often do you take ([numaspirin]) aspirin?	Month	
	Year	
	Unknown	

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Usual dose of aspirin (mg)?	<ul><li>81 mg - Baby</li><li>160 mg - Half</li><li>250 mg - e.g. Excedrin</li></ul>
	325 mg - Usual
	<ul><li>525 mg - Osuar</li><li>500 mg - Extra strength</li></ul>
	Other
	Unknown
	GIIRIOWII
Middle of continue II Others	
If dose of aspirin is "Other"	Aspirin dose in mg
Diagnoses and Tre	eatment Questions
High Blood Pressu	re or Hypertension
	◎ No
Have you been TOLD by your doctor you have high blood	© Yes
pressure or hypertension?	Unknown
	O No
Are you CURRENTLY TAKING MEDICATION for high blood pressure or hypertension?	<ul><li>Yes</li></ul>
pressure of hypertension.	Unknown
High Blood Cholester	ol or High Triglycerides
	No
Have you been TOLD by your doctor you have high blood	• Yes
cholesterol or high triglycerides?	Unknown
Are you CURRENTLY TAKING MEDICATION for bink blood	O No
Are you CURRENTLY TAKING MEDICATION for high blood cholesterol or high triglycerides?	Yes
5 57	Unknown
High Blood Su	gar or Diabetes
	© No
Have you been TOLD by your doctor you have high blood	○ Yes
sugar or diabetes?	Unknown
	O No
Are you CURRENTLY TAKING MEDICATION for high blood sugar or diabetes?	Yes
	Unknown

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#### **Cardiovascular Disease**

<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>	
al Comments	
	Yes Unknown

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# Framingham Heart Study

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### **Medications**

As Directed by F	As Directed by Physician or HCP			
In the PAST MONTH have you taken any <u>prescription</u> or <u>non-prescription</u> medication AS DIRECTED by physician or other health care provider?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>			
If "Yes"				
Medication bag with medications brought to exam?	<ul><li>No</li><li>Yes</li></ul>			
NOTE: For ASPIRIN ONLY - Do not code aspirin on this	page. CODE ON PRIOR PAGE M03			
Medication name #1				
Medication name #2				

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Medication name #3
Medication name #4
Medication name #5
Medication name #6
Medication name #7
Medication name #8
Medication name #9
Medication name #10
Medication name #11
Medication name #12
Medication name #13
Medication name #14
Medication name #15
Medication name #16
Medication name #17
Medication name #18

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Medication name #19	7
Medication name #20	_ ]
Are there any medications that you could not find on the drop down list?  No Yes	
Medication name #1 - not in drop down list	
Medication name #2 - not in drop down list	
Medication name #3 - not in drop down list	
Medication name #4 - not in drop down list	
Medication name #5 - not in drop down list	
Medication name #6 - not in drop down list	
Medication name #7 - not in drop down list	
Medication name #8 - not in drop down list	
Medication name #9 - not in drop down list	
Medication name #10 - not in drop down list	
Medication name #11 - not in drop down list	
Medication name #12 - not in drop down list	
Medication name #13 - not in drop down list	

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Medication name #14 - not in drop down list			
Medication name #15 - not in drop down list			
Medication name #16 - not in drop down list			
Medication name #17 - not in drop down list			
Medication name #18 - not in drop down list			
Medication name #19 - not in drop down list			
Medication name #20 - not in drop down list			
Over the Coun	ter Products (OTC)		
Are you taking over the counter products that are NOT DIRECTED by a physician or health care provider (i.e. vitamins, supplements, plant extracts, alternatives)?	No Yes Unknown		
Please answer all over the counter questions below:			
	No	Yes	
Vitamins	0	•	
Other	•	0	
Vaco	cinations		
Have you received an influenza vaccine (aka "flu shot") within the last year?	<ul><li>No</li><li>Yes</li><li>Maybe</li><li>Unknown</li></ul>		
Have you ever received a pneumovaccine?	<ul><li>No</li><li>Yes</li><li>Maybe</li><li>Unknown</li></ul>		

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#### **Additional Comments**

Medications			

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### Framingham Heart Study

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### **Female Reproductive History - Pregnancy**

Participant is male. Select "Save and go to Next Form".		
Check here to confirm study participant is female.	Yes, female	
Pregi	nancy	
Since your last exam ([lastexamdate]) have you taken or used birth control pills, shots, or hormone implants for birth control or medical indications (not post menopausal hormone replacement)?	<ul><li>No</li><li>Yes, now</li><li>Yes, not now</li><li>Unknown</li></ul>	
Have you ever tried to become pregnant for a year or more without becoming pregnant?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>	

	No
Have you ever used infertility treatment?	O Yes
•	Unknown
	O No
Have you been pregnant since your last exam ([lastexamdate])?	O Yes
([lastexamdate])?	Unknown
If "Yes"	
	One pregnancy
	<ul><li>Two pregnancies</li></ul>
	Three pregnancies
Number of pregnancies?	<ul><li>Four pregnancies</li></ul>
	Five pregnancies
	Six pregnancies
	<ul><li>Seven pregnancies</li></ul>
	O No
During any of these pregnancies, were you told you had high blood pressure or hypertension?	O Yes
	Unknown
	© No
During any of these pregnancies, were you told you	© Yes
had eclampsia, pre-eclampsia (toxemia)?	<ul><li>Unknown</li></ul>
	Olikilowii
	O No
During any of these pregnancies, were you told you	O Yes
had high blood sugar or diabetes?	<ul><li>Unknown</li></ul>
Have you had any live births since your last exam	No
([lastexamdate])?	Yes
If "Yes"	
	One baby
Number of live higher aires were last aver-	Two babies
Number of live births since your last exam ([lastexamdate])	Three babies
10 47	Four babies

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#### Questions about babies (born since last exam)

Now, I would like to ask you about how much each of your children (born after last exam) weighed at birth and whether you breastfed.

Baby #1					
Full terr	n?	<ul><li>Less than 37 weeks</li><li>37 weeks or more</li><li>Unknown</li></ul>			
Birth we	eight - (pounds)	99 = Unknown			
Birth we	eight - (ounces)	99 = Unknown			
	breast feed? e expressed breast milk)	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>			
If "Yes"					
Ho	ow long?	<ul><li>Less than 6 weeks</li><li>6 to 11 weeks</li><li>3 to 6 months</li><li>More than 6 months</li><li>Unknown</li></ul>			
Baby #2					
Full terr	n?	<ul><li>Less than 37 weeks</li><li>37 weeks or more</li><li>Unknown</li></ul>			
Birth we	eight - (pounds)	99 = Unknown			
Birth we	eight - (ounces)	99 = Unknown			
	breast feed? e expressed breast milk)	No Yes			

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If "Yes"	
	Less than 6 weeks
	6 to 11 weeks
How long?	3 to 6 months
<b>G</b>	More than 6 months
	Unknown
Baby #3	
	Less than 37 weeks
Full term?	37 weeks or more
	Unknown
Birth weight - (pounds)	
<b>.</b> ",	99 = Unknown
Birth weight - (ounces)	
Birti Weight - (Sunces)	99 = Unknown
	O No
Did you breast feed? (include expressed breast milk)	Yes
(include expressed breast fillin)	Unknown
If "Yes"	
	Less than 6 weeks
	6 to 11 weeks
How long?	3 to 6 months
	More than 6 months
	Unknown
Baby #4	
	Less than 37 weeks
Full term?	37 weeks or more
	Unknown
Birth weight - (pounds)	
	99 = Unknown
Birth weight - (ounces)	
g (5a	99 = Unknown

Did you breast feed? (include expressed breast milk)	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>	
If "Yes"		
	Less than 6 weeks	
	6 to 11 weeks	
How long?	3 to 6 months	
	More than 6 months	
	Unknown	
Additio	nal Comments	
Female Reproductive History - Pregnancy		

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#### Female Reproduction History - Menopause and Surgery

Darticipant	ic mala	Salact	"Save and	an to	<b>Next Form</b> "	
Participant	is maie.	Select	Save and	ao to	Next Form	

Check here to confirm study participant is female.

Yes, female

#### Menopause

What is the best way to describe your periods?

(Check the BEST answer)

- Not stopped answer D and E below
- Periods stopped due to pregnancy, breast feeding, or hormonal contraceptive (for example: depo-provera, progestin releasing IUD, extended release birth control pill)
   -answer D and E below
- Periods stopped due to low body weight, heavy exercise, or due to medication or health condition such as thyroid disease, pituitary tumor, hormone imbalance, stress answer A, D and E below
- Periods stopped for less than 1 year (perimenopausal)
   -answer B, D, E, F, G and H below
- Periods stopped for 1 year or more answer F, G and H below
- Periods stopped, but now have periods induced by hormones - answer C, F, G and H below

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#### If question is not applicable write "N/A"

A.) Write in CAUSE why periods stopped	
B.) NUMBER OF MONTHS since last period	99=Unknown
C.) NUMBER OF MONTHS periods stopped before hormones started	99 = Unknown
<ul><li>D.) WHEN was the first day of your last menstrual period?</li><li>(If first day of last menstrual period is unknown, enter 1/1/1900)</li></ul>	Today M-D-Y  1/1/1900 = Unknown
E.) HOW MANY periods have you had in past 12 months?	99=Unknown
F.) AGE when periods stopped  (If periods now induced by hormones, code age when periods naturally stopped. If perimenopausal, code age when periods stopped or became irregular.)	99=Unknown  Natural Surgical
G.) Was your menopause natural or the result of surgery, chemotherapy, or radiation? (If periods stopped for less than a year choose best answer.)	<ul><li>Chemo or radiation</li><li>Other</li><li>Unknown</li></ul>
H.) Have you since your last exam ([lastexamdate]) taken HORMONE REPLACEMENT THERAPY (estrogen or progesterone) or a selective estrogen receptor modulator (such as evista or raloxifene)?	<ul><li>No</li><li>Yes, now</li><li>Yes, not now</li><li>Unknown</li></ul>
Surgery	History
Since your last exam ([lastexamdate]) have you had a hysterectomy (uterus or womb removed)?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
If "Yes"	
Age at hysterectomy?	99=Unknown
Date of hysterectomy - Year	2002-2021, 9999 = Unknown
Date of hysterectomy - Month	1-12,

<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
99=Unknown
One ovary
<ul><li>Two ovaries</li></ul>
Part of an ovary
<ul><li>Unknown number of ovaries</li></ul>
I Comments

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### **Smoking**

Cigarettes			
Since your last exam ([lastexamdate]) have you smoked cigarettes regularly?	No Yes Unknown		
If "Yes"			
Have you smoked cigarettes regularly in the LAST YEAR?	<ul><li>No or less than 1 cigarette a day per year</li><li>Yes</li><li>Unknown</li></ul>		
Do you now smoke cigarettes (as of 1 month ago)?	No Yes Unknown		

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How many cigarettes do you smoke per day now?	noke per day now?
now many digarettes do you smoke per day now:	99 = Unknown
Questions below refer to "whole lifetime"	
On the average of the entire time you smoked, how	
many cigarettes did you smoke per day?	99 = Unknown
How old were you when you first started regular cigarette smoking?	99 = Unknown
If you have stopped smoking cigarettes completely, how old were you when you stopped?	00 = Not stopped, 99 = Unknown
When you were smoking, did you ever stop smoking for more than 6 months?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
If "Yes"	
For how many years in total did you stop smoking cigarettes?	# of years, 1 = 6 months - 12 months, 99 = Unknown
Pipes o	r Cigars
	O No
Since your last exam ([lastexamdate]) have you regularly	O Yes
smoked a pipe or cigar?	Unknown
If "Yes"	
	O No
Do you smoke a pipe or cigar now?	Yes
,	Unknown
E-ciga	rettes
E-cigarettes are battery-powered and produce vapor instead	of smoke.
	O No
Have you ever tried an e-cigarette?	Yes
- <del>-</del>	Unknown

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ave you ever been a regular user of e-cigarettes? at least once per week)	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
"Yes"	
How long did you use e-cigarettes? - months	999 = Unknown
How many days per week, on average, did you use e-cigarettes while you were a regular user?	# of days per week, 1 = 1 day or less per week, 9 = Unknown
In the past 5 days, including today, on how many days did you smoke an e-cigarette?	<ul> <li>0 days</li> <li>1 day</li> <li>2 days</li> <li>3 days</li> <li>4 days</li> <li>5 days</li> <li>Refused to answer</li> <li>Don't know</li> </ul>
Additional	Comments

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### **Alcohol Consumption**

Now I will ask you questions regarding your alcohol	Luca	
Now I will ask you questions regarding your alcohol	use.	
	No	
Do you drink beer at least once a month?	Yes	
(serving 12 oz. bottle, glass, can)	Unknown	
If "Yes"		
Do you drink beer at least once week?	No	
	Yes	
	Unknown	
If "Yes"		
Number of beers per week		
	000 Unknown	

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If "No"	
Number of beers per month	999 = Unknown
Do you drink wine at least once a month? (serving red or white, 4oz. glass)	No Yes Unknown
If "Yes"	
Do you drink wine at least once a week?	No Yes Unknown
If "Yes"	
Number of glasses of wine per week	999 = Unknown
If "No"	
Number of glasses of wine per month	999 = Unknown
Do you drink liquor or spirits at least once a month? (serving 1 oz. cocktail or highball)	No Yes Unknown
If "Yes"	
Do you drink liquor or spirits at least once per week?	No Yes Unknown
If "Yes"	
Number of liquor or spirit drinks per week	999 = Unknown
If "No"	
Number of liquor or spirit drinks per month	999 = Unknown
At what age did you stop drinking alcohol?  00 = IF NOT STOPPED  888 = NEVER DRINKER	00 = If not stopped, 888 = Never drinker, 999 = Unknown

Over the past year, on average, on how many days per week did you drink an alcoholic beverage of any type?	0 = No days, 1 = 1 day or less, 9 = Unknown
Over the past year, on a typical day when you drink, how many drinks do you have?	0 = No drinks, 1 = 1 or less, 99 = Unknown
What was the maximum number of drinks you had in a 24 hour period during the past month?	0 = No drinks, 1 = 1 or less, 99 = Unknown
Since your last exam has there been a time when you drank 5 or more alcoholic drinks of any kind almost daily?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
Examiner Opinion:  Over the past year, does participant report drinking less than one alcoholic drink of any type per month?  (include current non-drinkers)	Yes
(motude current non-uninters)	
Additional	Comments
Alcohol Consumption	

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### **Respiratory Symptoms**

Cough		
Do you usually have a cough? - Exclude clearing of the throat	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>	
Do you usually have a cough at all on getting up or first thing in the morning?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>	
If "Yes" to either of the two questions directly above		
Do you cough like this on most days for three consecutive months or more during the past year?	No Yes Unknown	

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How many years have you had this cough?	Number of years, 1 = 1 year or less, 99 = Unknown
Phl	egm
Do you usually bring up phlegm from your chest?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
Do you usually bring up phlegm at all on getting up or first thing in the morning?	No Yes Unknown
If "Yes" to either of 2 questions directly above	
Do you bring up phlegm from your chest on most days for three consecutive months or more during the year?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
How many years have you had trouble with phlegm?	Number of years, 1 = 1 year or less, 99 = Unknown
Who	eeze
In the past 12 months	
Have you had wheezing or whistling in your chest at any time?	No Yes Unknown
If "Yes"	
How often have you had this wheezing or whistling?	<ul> <li>MOST days or nights</li> <li>A few days or nights a WEEK</li> <li>A few days or nights a MONTH</li> <li>A few days or nights a YEAR or less</li> <li>Unknown</li> </ul>
Have you had this wheezing or whistling in the chest when you had a cold?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>

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	<ul><li>No</li></ul>
Have you had this wheezing or whistling in the chest apart from colds?	Yes
	Unknown
	No
Have you had an attack of wheezing or whistling in	Yes
the chest that made you feel short of breath?	Unknown
Additional	Comments
piratory Symptoms	

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### **Sleep Apnea and CHF Opinion**

Sleep Related Symptoms (days/ nights)		
In the past 12 months		
On average how many nights a week did you snore?	Never	
	Rarely (1-2 nights/week)	
	Occasionally (3-4 nights/week)	
	Frequently (5 or more nights/week)	
	I don't know	
	Unknown	
		rese

On average, how many nights a week do you snort, gasp, or stop breathing while you are asleep?	<ul> <li>Never</li> <li>Rarely (1-2 nights/week)</li> <li>Occasionally (3-4 nights/week)</li> <li>Frequently (5 or more nights/week)</li> <li>I don't know</li> <li>Unknown</li> </ul>
On average, how many days a week have you had excessive (too much) daytime sleepiness?	<ul> <li>Never</li> <li>Rarely (1-2 days/week)</li> <li>Occasionally (3-4 days/week)</li> <li>Frequently (5 or more days/week)</li> <li>I don't know</li> <li>Unknown</li> </ul>
Nocturnal Che	est Symptoms
Since your last exam ([lastexamdate])	
Have you been awakened by shortness of breath?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
Have you been awakened by coughing?	No Yes Unknown
Shortness	s of Breath
Since your last exam ([lastexamdate])	
Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
If "Yes"	
Do you have to walk slower than people of your age on level ground because of shortness of breath?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>

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Do you have to stop for breath when walking at your own pace on level ground?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
Do you have to stop for breath after walking 100 yards (or after a few minutes) on level ground?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
Do you or have you needed to sleep on two or more pillows to help you breathe (orthopnea)?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
Have you had swelling in both your ankles (ankle edema)?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
Have you been told by your doctor you had heart failure or congestive heart failure?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
If "Yes"	
Have medical encounter details been entered on M01 Medical Encounters?	O No O Yes
If "No"	
Name of doctor	
Location of doctor	City, state
Date of visit - year	9999 = Unknown
DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	
Have you been hospitalized or visited the E.R. for heart failure?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>

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f "Yes"	
Have medical encounter details been entered on M01 Medical Encounters?	<ul><li>No</li><li>Yes</li></ul>
If "No"	
Name of hospital	
Location of hospital	City, state
Date of hospitalization - year	9999 = Unknown
DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	
CHF First Exa	miner Opinion
First Examiner believes CHF	No Yes Maybe Unknown
Additional	Comments
Sleep Apnea and CHF Opinion	

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### **Blood Pressure 1st MD Reading**

BP cuff size	Pediatric
	Regular adult
	Large adult
	Thigh
	Unknown
	O No
Protocol modification	O Yes
	Unknown
If "Yes"	
Comments for protocol modification	

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Systolic (to nearest 2 mmHg)	999 = Unknown
Diastolic (to nearest 2 mmHg)	999 = Unknown
	Additional Comments
Blood Pressure 1st MD Reading	

M10 - BP 1st MD Reading

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### **Chest Discomfort and CHD Opinion**

Since you last provided medical information ([lastmedint	fodate])
Have you experienced any CHEST DISCOMFORT?	No
	Yes
	Maybe
	Unknown
If "Yes" or "Maybe"  In addition to answering the questions, pr	ovide narrative comments in box below.
Chest discomfort with exertion or excitement	O No
	Yes
	Maybe
	Unknown

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	O No
Chest discomfort when quiet or resting	Yes
	Maybe
	Unknown
Chest Discomfort Characteristics	
Date of onset - year	
Jule of officer your	2002-2021, 9999 = Unknown
DATE details	
(e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	
Usual duration (minutes)	1 = 1 min or less, 900 = 15 hrs or more,
	999 = Unknown
Longest duration (minutes)	1 = 1 min or less,
	900 = 15 hrs or more, 999 = Unknown
	O No
	<ul><li>Central sternum and upper chest</li></ul>
	<ul><li>Left upper quadrant</li></ul>
	Left lower ribcage
Location	Right chest
	Other
	Combination
	Unknown
	O No
	Left shoulder or left arm
	Neck
	Right shoulder or right arm
Radiation	Back
	Abdomen
	Other
	Combination
	Unknown

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Number of episodes of chest pain in past year		999 = Unknown		
		999 = Unknown		
Туре		<ul><li>Pressure, heave</li><li>Sharp</li><li>Dull</li><li>Other</li><li>Unknown</li></ul>	y, vise	
	No	Yes	Not tried	Unknown
Relief by nitroglycerin in < 15 minutes	•	•	•	0
Relief by rest in < 15 minutes	0	0	0	0
Relief spontaneously in < 15 minutes	0	0	0	0
Relief by other cause in < 15 minutes	0	0	0	•
Since you last provided medical information	on ([lastmedinfod	ate])		
Have you been told by a doctor you had a heart attack, myocardial infarction or angina?		<ul><li>No</li><li>Yes</li><li>Maybe</li><li>Unknown</li></ul>		
If "Yes" or "Maybe"				
Have medical encounter details been entered on M01 Medical Encounters?		<ul><li>No</li><li>Yes</li></ul>		
If "No"				
Name of doctor				
Location of doctor		City, State		
Date of visit - year		2002-2021, 9999 = Unknown		
DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)				

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Since you last provided medical information ([lastmedinfodate])		
Have you been to a hospital or visited the ER for a heart attack, myocardial infarction or angina?	<ul><li>No</li><li>Yes</li><li>Maybe</li><li>Unknown</li></ul>	
If "Yes" or "Maybe"		
Have medical encounter details been entered on M01 Medical Encounters?	<ul><li>No</li><li>Yes</li></ul>	
If "No"		
Name of hospital		
Location of hospital	City, State	
Date - year	2002-2021, 9999 = Unknown	
DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)		
CHD First Exa	miner Opinions	
Angina pectoris	<ul><li>No</li><li>Yes</li><li>Maybe</li><li>Unknown</li></ul>	
If "Yes" or "Maybe"		
Angina pectoris since revascularization procedure?	<ul><li>No</li><li>Yes</li><li>Maybe</li><li>Unknown</li></ul>	
Coronary insufficiency	<ul><li>No</li><li>Yes</li><li>Maybe</li><li>Unknown</li></ul>	

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	No			
	O Yes			
Myocardial infarct	Maybe			
	Unknown			
Additional Comments				
Chest Discomfort and CHD Opinion				

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### **Atrial Fibrillation, Syncope & Syncope Opinion**

Atrial Fibrillation			
Since your last provided medical information ([lastmedinfo	date])		
Have you been told you have or have had atrial fibrillation (or atrial flutter)?	O No		
	O Yes		
	<ul><li>Maybe</li></ul>		
	Unknown		
If "Yes" or "Maybe"			
Year of first episode since [lastmedinfodate]	2002-2021, 9999 = Unknown		
DATE details of first episode since [lastmedinfodate] (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)			

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Hospitalized, ER or saw M.D.	<ul><li>No</li><li>Hospitalized or ER</li><li>Saw M.D.</li><li>Unknown</li></ul>			
If "Hospitalized or ER" or "Saw M.D."				
Have medical encounter details been entered on M01 Medical Encounters?	<ul><li>No</li><li>Yes</li></ul>			
If "No"				
Name of hospital				
Location of hospital	City, State			
Name of doctor				
Location of doctor	City, State			
Year	2002-2021, 9999 = Unknown			
DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)				
Syncope				
Since your last exam ([lastexamdate])	-			
Have you fainted or lost consciousness? (If event immediately preceded by head injury or accident, code as "No")	<ul><li>No</li><li>Yes</li><li>Maybe</li><li>Unknown</li></ul>			
If "Yes" or "Maybe"				
Year of first episode since [lastexamdate]	2002-2021, 9999 = Unknown			
DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)				
Number of episodes in the past two years	999=Unknown			
Usual duration of loss of consciousness - minutes	1=1 min or less 999=Unknown			

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Did you have any injury caused by the event?	<ul><li>No</li><li>Yes</li><li>Maybe</li><li>Unknown</li></ul>
Hospitalized, ER or saw M.D. for fainting or loss of consciousness	<ul><li>No</li><li>Hospitalized or ER</li><li>Saw M.D.</li><li>Unknown</li></ul>
If "Hospitalized or ER" or "Saw M.D."	
Have medical encounter details been entered on M01 Medical Encounters?	<ul><li>No</li><li>Yes</li></ul>
If "No"	
Name of hospital	
Location of hospital	City, State
Name of M.D.	
Location of doctor	City, State
Year	2002-2021, 9999 = Unknown
DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	
Have you had a head injury with loss of consciousness?	<ul><li>No</li><li>Yes</li><li>Maybe</li><li>Unknown</li></ul>
If "Yes" or "Maybe"	
Have medical encounter details been entered on M01 Medical Encounters?	<ul><li>No</li><li>Yes</li></ul>
If "No"	
Year	2002-2021, 9999 = Unknown

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DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	
Have you had a seizure?	<ul><li>No</li><li>Yes</li><li>Maybe</li><li>Unknown</li></ul>
If "Yes" or "Maybe"	
Year of most recent seizure since [lastmedinfodate]	2002-2021, 9999 = Unknown
DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	
Hospitalized, ER or saw M.D.	<ul><li>No</li><li>Hospitalized or ER</li><li>Saw M.D.</li><li>Unknown</li></ul>
If "Hospitalized or ER" or "Saw M.D."	
Have medical encounter details been entered on M01 Medical Encounters?	<ul><li>No</li><li>Yes</li></ul>
If "No"	
Name of hospital	
Location of hospital	City, State
Name of doctor	
Location of doctor	City, State
Year	2002-2021, 9999 = Unknown
DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	
Are you being treated for a seizure disorder?	<ul><li>No</li><li>Yes</li><li>Maybe</li><li>Unknown</li></ul>

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pe First Examiner Opinion	
No	
O Yes	
Maybe	
Presyncope	
Unknown	
No	
Yes	
Maybe	
Unknown	
O No	
Yes	
Maybe	
Unknown	
No	
Yes	
Maybe	
Unknown	
Additional Comments	
	No Yes Maybe Presyncope Unknown  No Yes Maybe Unknown  No Yes Maybe Unknown  No Yes Maybe Unknown  Unknown  No Yes Maybe Unknown

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#### **Cerebrovascular Disease and Opinion**

#### **Cerebrovascular Disease**

Since you last provided medical information ([lastmedinfodate]) have you had . . .

	No	Yes	Maybe	Unknown
Sudden muscular weakness	•	•	•	0
Sudden speech difficulty	0	0	0	•
Sudden visual defect	0	0	0	0
Sudden double vision	0	0	0	0
Sudden loss of vision in one eye	0	0	0	•
Sudden numbness, tingling	0	0	0	0

If "Yes" or "Maybe"	
	No
	Yes
Numbness and tingling is positional	Maybe
	Unknown
	O No
LIFAD CT OTHER THAN FOR THE FUR	<ul><li>Yes</li></ul>
HEAD CT scan OTHER THAN FOR THE FHS	Maybe
	Unknown
If "Yes" or "Maybe"	
Have medical encounter details been entered on M01 Medical Encounters?	No
	Yes
If "No"	
Name of facility	
Location of facility	
Location of facility	City, State
Date - year	
Suite your	2002-2021, 9999 = Unknown
DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	
	No
	• Yes
HEAD MRI scan OTHER THAN FOR THE FHS	Maybe
	Unknown
If "Yes" or "Maybe"	
Have medical encounter details been entered on M01 Medical Encounters?	No
	• Yes
If "No"	
Name of facility	
Location of facility	City, State

Date - year		2002-2021, 9999 = Unknown		
DATE details (e.g. 10/2, April, Summer, August-Nov., U	Jnknown etc.)			
Seen by neurologist		No Yes Maybe Unknown		
If "Yes" or "Maybe"				
Have medical encounter details been Medical Encounters?	entered on M01	<ul><li>No</li><li>Yes</li></ul>		
If "No"				
Name of neurologist				
Location of neurologist		City, State		
Date - year				
Date year		2002-2021, 9999 = Unknown		
DATE details (e.g. 10/2, April, Summer, August-Nov., U	Jnknown etc.)			
DATE details	Jnknown etc.) No		Maybe	Unknown
DATE details	<u> </u>	9999 = Unknown	Maybe	Unknown
DATE details (e.g. 10/2, April, Summer, August-Nov., Use the second seco	No	9999 = Unknown Yes		
DATE details (e.g. 10/2, April, Summer, August-Nov., to the second secon	No	Yes	0	•
DATE details (e.g. 10/2, April, Summer, August-Nov., Use the control of the contr	No ©	Yes	•	•

Cerebrovascular Disease First Examiner Opinion		
TIA or STROKE took place	<ul><li>No</li><li>Yes</li><li>Maybe</li><li>Unknown</li></ul>	
If "Yes" or "Maybe"		
Date of TIA or STROKE - year	2002-2021, 9999 = Unknown	
DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)		
Observed by		
Total duration of TIA or STROKE = # days + # hours + #	minutes	
Duration - number of days	99 = Unknown	
Duration - number of hours	0 - 23, 99 = Unknown	
Duration - number of minutes	0 - 59, 99 = Unknown	
Hospitalized or saw MD	<ul><li>No</li><li>Hospitalized or ER</li><li>Saw MD</li><li>Unknown</li></ul>	
If "Hospitalized or ER" or "Saw MD"		
Have medical encounter details been entered on M01 Medical Encounters?	<ul><li>No</li><li>Yes</li></ul>	
If "No"		
Name of hospital		
Location of hospital	City, State	
Name of doctor		
Location of doctor	City, State	

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Date - year	2002-2021, 9999 = Unknown
DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	
Additional	Comments
rebrovascular Disease and Opinion	

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# Venous and Peripheral Arterial Disease and Intermittent Claudication Opinion

Venous Disease Since you last provided medical information ([lastmedinfodate]) have you had		
	O Yes	
Deep vein thrombosis - DVT (blood clots in legs or arms)	Maybe	
	Unknown	
	O No	
	O Yes	
Pulmonary embolus - PE (blood clot in lungs)	<ul><li>Maybe</li></ul>	
	Unknown	

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Peripheral Arterial Disease		
Since you last provided medical information ([lastmedinfodate])		
Do you get discomfort in either leg on walking?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>	
If "Yes"		
Does this discomfort ever begin when you are standing still or sitting?	No Yes Unknown	
When walking at an ordinary pace on level ground, how many city blocks until symptoms develop?  (where 10 blocks = 1 mile)  0 = more than 98 blocks required to develop symptoms, 1 = 1 block or less, 99 = Unknown		evelop symptoms,
Claudication	n Symptoms	
Discomfort while walking		
No	Yes	Unknown
CALF - left	•	•
CALF - right	0	•
NOT CALF - left lower extremity	0	•
NOT CALF - right lower extremity	0	0
If "Yes" discomfort NOT CALF - left or right		
Write in site of discomfort		
Occurs with first steps (code worse leg)	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>	
Do you get the discomfort when you walk up a hill or hurry?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>	
Does the discomfort ever disappear while you are still walking?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>	

What do you do if you get discomfort when you are walking?	<ul><li>Stop</li><li>Slow down</li><li>Continue at same pace</li><li>Unknown</li></ul>
Time for discomfort to be relieved by stopping (minutes)	0 = No relief with stopping, 999 = Unknown
Number of days per month of lower limb discomfort	1 = 1 day/month or less, 99 = Unknown
Since your last exam ([lastexamdate]) have you been told by a doctor you have intermittent claudication or peripheral artery disease?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
If "Yes"	
Have medical encounter details been entered on M01 Medical Encounters?	<ul><li>No</li><li>Yes</li></ul>
lf "No"	
Name of doctor	
Location of doctor	City, State
Date of visit - year	2002-2021, 9999 = Unknown
DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	
Since your last exam ([lastexamdate]) have you been told by a doctor you have spinal stenosis?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
Intermittent Claudication First Examiner Opinion	
Intermittent claudication	<ul><li>No</li><li>Yes</li><li>Maybe</li><li>Unknown</li></ul>

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# Additional Comments Venous and Peripheral Arterial Disease and Intermittent Claudication Opinion

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### **CVD Procedures**

Since you last provided medical information ([la	stmedinfodate])	
Did you have any of the following cardiovascular procedures?		
(if procedure was repeated, code only FIRST and provide narrative)		
Heart valvular surgery	No	
	Yes	
	Maybe	
	Unknown	
If "Yes" or "Maybe"		
YEAR - Heart valvular surgery		
	2002 - 2021, 9999 = Unknown	

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Exercise stress test or other type of cardiac stress test	<ul><li>No</li><li>Yes</li><li>Maybe</li><li>Unknown</li></ul>
If "Yes" or "Maybe"	
YEAR - Exercise stress test	2002 - 2021, 9999 = Unknown
Coronary arteriogram	<ul><li>No</li><li>Yes</li><li>Maybe</li><li>Unknown</li></ul>
If "Yes" or "Maybe"	
YEAR - Coronary arteriogram	2002 - 2021, 9999 = Unknown
Coronary artery angioplasty or stent	<ul><li>No</li><li>Yes</li><li>Maybe</li><li>Unknown</li></ul>
If "Yes" or "Maybe"	
YEAR - Coronary artery angioplasty or stent	2002 - 2021, 9999 = Unknown
Coronary bypass surgery	<ul><li>No</li><li>Yes</li><li>Maybe</li><li>Unknown</li></ul>
If "Yes" or "Maybe"	
YEAR - Coronary bypass surgery	2002 - 2021, 9999 = Unknown
Permanent pacemaker insertion	<ul><li>No</li><li>Yes</li><li>Maybe</li><li>Unknown</li></ul>

If "Yes" or "Maybe"	
YEAR - Permanent pacemaker insertion	2002 - 2021, 9999 = Unknown
Carotid artery surgery or stent	<ul><li>No</li><li>Yes</li><li>Maybe</li><li>Unknown</li></ul>
If "Yes" or "Maybe"	
YEAR - Carotid artery surgery or stent	2002 - 2021, 9999 = Unknown
Thoracic aorta surgery	<ul><li>No</li><li>Yes</li><li>Maybe</li><li>Unknown</li></ul>
If "Yes" or "Maybe"	
YEAR - Thoracic aorta surgery	2002 - 2021, 9999 = Unknown
Abdominal aorta surgery	<ul><li>No</li><li>Yes</li><li>Maybe</li><li>Unknown</li></ul>
If "Yes" or "Maybe"	
YEAR - Abdominal aorta surgery	2002 - 2021, 9999 = Unknown
Femoral or lower extremity surgery	<ul><li>No</li><li>Yes</li><li>Maybe</li><li>Unknown</li></ul>
If "Yes" or "Maybe"	
YEAR - Femoral or lower extremity surgery	2002 - 2021, 9999 = Unknown

Lower extremity amputation	<ul><li>No</li><li>Yes</li><li>Maybe</li><li>Unknown</li></ul>	
If "Yes" or "Maybe"		
YEAR - Lower extremity amputation	2002 - 2021, 9999 = Unknown	
Other cardiovascular procedure (specify below)	<ul><li>No</li><li>Yes</li><li>Maybe</li><li>Unknown</li></ul>	
If "Yes" or "Maybe"		
YEAR - Other cardiovascular procedure	2002 - 2021, 9999 = Unknown	
Specify other cardiovascular procedure		
Write in other procedures, year done, location if more than one.		
Additional Comments		
CVD Procedures		

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### **Blood Pressure 2nd MD Reading**

	Pediatric	
	Regular adult	
BP cuff size	Large adult	
	Thigh	
	Unknown	
Protocol modification	No	
	Yes	
	Unknown	
If "Yes"		
Comments for protocol modification		

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Systolic (to nearest 2 mmHg)		
Diastolic (to nearest 2 mmHg)		
Additional Comments		
Blood Pressure 2nd MD Reading		

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### Cancer

	O No
Since your last provided medical information	O Yes
([lastmedinfodate]) have you had a cancer or tumor?	Maybe
	Unknown
If "Yes" or "Maybe"	
	Bladder
	Brain
	Breast
	Cervix/Uteru
Cancer or tumor - #1	Colon/Rectum
	Esophagus
	Kidney
	Larynx
	Leukemia

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	◎ No
	Yes
Have you had a second cancer or tumor?	Maybe
	Unknown
If "Yes" or "Maybe"	
	0.00
	Bladder
	Brain
	Breast
	O Cervix/Uteru
	Ocolon/Rectum
	Esophagus
	Kidney
	Larynx
Cancer or tumor - #2	Leukemia
Cancer of turnor - #2	Lymphoma
	Ovary
	Pancreas
	Prostate
	Skin
	Stomach
	Thyroid
	<ul><li>Trachea/Bronchus/Lung</li></ul>
	Other
Cancer or tumor site for "Other" - #2 ([cancersite2])	
	Cancer
Diagnosis - #2 ([cancersite2])	Maybe cancer
J u J	Benign
	◎ No
Have medical encounter details been entered on M01 Medical Encounters - #2 ([cancersite2])	Yes
Medical Encounters - #2 ([cancersite2])	- 103
If "No"	
Year first diagnosed - #2 ([cancersite2])	2002-2021, 9999 = Unknown
DATE details - #2 ([cancersite2]) (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	
Name of MD - #2 ([cancersite2])	

Location of MD - #2 ([cancersite2])	City, State	
Was a diagnostic biopsy done at a different location? - #2 ([cancersite2])	<ul><li>No</li><li>Yes</li></ul>	
If "Yes"		
Year of biopsy - #2 ([cancersite2])	2002-2021, 9999 = Unknown	
DATE details for biopsy - #2 ([cancersite2]) (e.g. 10/2, April, Summer, August-Nov., Unknown etc)		
Name of MD for biopsy - #2 ([cancersite2])		
Location of biopsy - #2 ([cancersite2])	City, State	
Have you had a third cancer or tumor?	<ul><li>No</li><li>Yes</li><li>Maybe</li><li>Unknown</li></ul>	
If "Yes" or "Maybe"		
Cancer or tumor - #3	<ul> <li>Bladder</li> <li>Brain</li> <li>Breast</li> <li>Cervix/Uteru</li> <li>Colon/Rectum</li> <li>Esophagus</li> <li>Kidney</li> <li>Larynx</li> <li>Leukemia</li> <li>Lymphoma</li> <li>Ovary</li> <li>Pancreas</li> <li>Prostate</li> <li>Skin</li> <li>Stomach</li> <li>Thyroid</li> <li>Trachea/Bronchus/Lung</li> <li>Other</li> </ul>	
Cancer or tumor site for "Other" - #3 ([cancersite3])		

	O Cancer
Diagnosis - #3 ([cancersite3])	Maybe cancer
Diagnosis - #3 ([cancersite3])	Benign
	Delligh
	© No
Have medical encounter details been entered on M01	• Yes
Medical Encounters - #3 ([cancersite3])	Tes
If "No"	
Year first diagnosed - #3 ([cancersite3])	2002-2021,
	9999 = Unknown
DATE details - #3 ([cancersite3])	
(e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	
Name of MD - #3 ([cancersite3])	
Location of MD - #3 ([cancersite3])	City State
	City, State
Was a diagnostic biopsy done at a different	O No
location? - #3 ([cancersite3])	<ul><li>Yes</li></ul>
K IIVoo II	
If "Yes"	
Vegraf bioney #2 (Iconograite21)	
Year of biopsy - #3 ([cancersite3])	2002-2021, 9999 = Unknown
DATE details for bissess #0 (for second to 01)	7777 - UIINIUWII
DATE details for biopsy - #3 ([cancersite3]) (e.g. 10/2, April, Summer, August-Nov., Unknown etc)	
Name of MD for biopsy - #3 ([cancersite3])	
Location of biopsy - #3 ([cancersite3])	
Location of Stopsy #0 ([cancerstices])	City, State
	No
	Yes
Have you had a fourth cancer or tumor?	Maybe
	Unknown
	Olikilowii
If "Yes" or "Maybe"	
	Bladder
	Brain
	Breast
Cancer or tumor - #4	
	Cervix/Uteru
	Oclon/Rectum
	<ul><li>Esophagus</li></ul>

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		Lympnoma	
		Ovary	
		<ul><li>Pancreas</li></ul>	
		Prostate	
		Skin	
		Stomach	
		Thyroid	
		<ul><li>Trachea/Bronchus/Lung</li></ul>	
		Other	
Cancer or tumor site for "Other" -	- #4 ([cancersite4])		
		Cancer	
Diagnosis - #4 ([cancersite4])		Maybe cancer	
Diagnosis - #4 ([cancersite4])		<ul><li>Benign</li></ul>	
		•	
Have medical encounter details b	neen entered on MO1	<ul><li>No</li></ul>	
Medical Encounters - #4 ([cancers		<ul><li>Yes</li></ul>	
If "No"			
Year first diagnosed - #4 ([ca	ancersite4])	2002-2021, 9999 = Unknown	
DATE details #4 (Feeneausi	4-41\	9999 = UIIKIIUWII	
DATE details - #4 ([cancersit (e.g. 10/2, April, Summer, August-N			
Name of MD - #4 ([cancersite	e41)		
Tumo or mo market (goallooren)			
Location of MD - #4 ([cancer	rsite4])		
	<del></del>	City, State	
Was a diagnostic biopsy do	ne at a different	No	
location? - #4 ([cancersite4]		Yes	
If "Yes"			
<b>V</b>	470		
Year of biopsy - #4 ([ca	incersite4])	2002-2021,	
DATE LOUIS COLUMN	на п	9999 = Unknown	
DATE details for biops (e.g. 10/2, April, Summer, Au			
Name of MD for biopsy			
Haine of Mid for biopsy	- <del> ([</del> Cancersite4])		

KidneyLarynxLeukemia

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Location of biopsy - #4 ([cancersite4])	
	City, State
Have you had a fifth cancer or tumor?	O No
	O Yes
	Maybe
	Unknown
f "Yes" or "Maybe"	
	Bladder
	Brain
	<ul><li>Breast</li></ul>
	Cervix/Uteru
	Ocolon/Rectum
	<ul><li>Esophagus</li></ul>
	Kidney
	Larynx
	<ul><li>Leukemia</li></ul>
Cancer or tumor - #5	Lymphoma
	Ovary
	Pancreas
	Prostate
	Skin
	Stomach
	Thyroid
	Trachea/Bronchus/Lung
	Other
Cancer or tumor site for "Other" - #5 ([cancersite5])	
	Cancer
Diagnosis - #5 ([cancersite5])	Maybe cancer
	<ul><li>Benign</li></ul>
Have medical encounter details been entered on M01	© No
Medical Encounters - #5 ([cancersite5])	O Yes
If "No"	
Year first diagnosed - #5 ([cancersite5])	2002-2021, 9999 = Unknown
DATE details - #5 ([cancersite5])	
(e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	

Name of MD - #5 ([cancersite5])	
Location of MD - #5 ([cancersite5])	City, State
Was a diagnostic biopsy done at a different location? - #5 ([cancersite5])	<ul><li>No</li><li>Yes</li></ul>
If "Yes"	
Year of biopsy - #5 ([cancersite5])	2002-2021, 9999 = Unknown
DATE details for biopsy - #5 ([cancersite5]) (e.g. 10/2, April, Summer, August-Nov., Unknown etc)	
Name of MD for biopsy - #5 ([cancersite5])	
Location of biopsy - #5 ([cancersite5])	City, State
Additional	I Comments
Cancer	

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### **ECG**

For	OFF	SITE	avame

- ECG is completed by MD after exam form is returned to FHS site.
- TECH ONLY if exam is OFFSITE, select "SAVE and go to Next Form".

OFFSITE ONLY		
MD ID#		abla

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	Rhythm
Rhythm - predominant	<ul> <li>Normal sinus (including s. tach, s. brady, s. arrhy, 1 degre AV block)</li> </ul>
	2nd degree AV block, Mobitz I (Wenckebach)
	2nd degree AV block, Mobitz II
	3rd degree AV block / AV dissociation
	Atrial fibrillation / atrial flutter
	Nodal
	Paced
	Other or combination of above (list)
If "Other or combination of above (list)"	
Specify combination	
Ventricular	Conduction Abnormalities
	O No
IV block	Yes
	<ul><li>Fully paced or Unknown</li></ul>
If "Yes"	
	Left
Dettern	Right
Pattern	Indeterminate
	Unknown
	<ul><li>Incomplete (QRS interval &lt; .12 sec)</li></ul>
IV block complete or incomplete	Complete (QRS interval >= .12 sec)
Stock complete of moomplete	Unknown
	O No
	<ul><li>Left anterior</li></ul>
Hemiblock	Left posterior
	<ul><li>Fully paced or Unknown</li></ul>

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	O No
WPW syndrome	O Yes
WFW Syndrome	Maybe
	Fully paced or Unknown
Arrhyt	hmias
	O No
Add to the second of the secon	O Atrial
Atrial premature beats	Atrial aberrant
	Unknown
	O No
	Simple
	Multifoc.
Ventricular premature beats	Pairs
•	Run
	R on T
	Unknown
Number of ventricular premature beats in 10 seconds	
(see 10 second rhythm strip)	99 = Unknown
Myocardial Infa	rction Location
	O No
	O Yes
Anterior	<ul><li>Maybe</li></ul>
	Fully paced or Unknown
	O No
	O Yes
Inferior	Maybe
	Fully paced or Unknown

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No Yes True posterior Maybe Fully paced or Unknown Hypertrophy, Enlargement, and Other ECG Diagnoses No S-T depression S-T flattening Nonspecific S-T segment abnormality Other Fully paced or Unknown No T inversion T flattening Nonspecific T-wave abnormality Other Fully paced or Unknown None Left Right Atrial enlargement Both Atrial fibrillation or Unknown No **RVH** Yes If complete RBBB or LBBB present, Maybe code RVH = Unknown Fully paced or Unknown No LVH LVH with strain LVH with mild S-T segment abnormality If complete LBBB present, LVH by voltage only code LVH = Unknown Fully paced or Unknown **LVH VOLTAGE CRITERIA** R > 20mm in any limb lead R > 11mm in AVL R in lead I plus S in lead III >= 25mm R in V5 or V6 --- S in V1 or V2 R >= 25mm S >= 25mm R or S <= 30mm

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R + S >= 35mm

Additional Comments		
ECG		

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### **Clinical Diagnostic Impression**

Heart Diagnoses				
	No	Yes	Maybe	Unknown
Aortic valve disease	•	•	•	•
Mitral valve disease	•	•	0	•
	Neurologi	cal Disease		
	No	Yes	Maybe	Unknown
Dementia	•	0	•	0
Parkinson's Disease	•	•	0	0
Adult seizure disorder	0	0	0	0
Migraine	•	0	•	0
Other neurological disease	0	0	0	0

Specify other neurological disease				
Additional comments for neurological dis	sease			
	Ende	ocrine		
	No	Yes	Maybe	Unknown
Thyroid disease	0	•	•	0
Diabetes Mellitus	0	•	•	0
Other endocrine disorders	0	•	•	0
Specify other endocrine disorders				
	GU/	GYN		
	No	Yes	Maybe	Unknown
Renal disease	0	•	0	•
Specify renal disease				
	No	Yes	Maybe	Unknown
Prostate disease	0	•	0	0
	No	Yes	Maybe	Unknown
Gynecological problems	0	•	•	0
Specify gynecological problems				

### **Pulmonary**

	No	Yes	Maybe	Unknown
Emphysema	•		•	0
Pneumonia	0	0	0	0
Asthma	0	0	0	0
Obstructive sleep apnea	•	0	0	0
Other pulmonary disease	0	0	0	0
Specify other pulmonary disease				
	Rheumatolo	gic Disorders		
	No	Yes	Maybe	Unknown
Gout	•	0	0	0
Degenerative joint disease	0	0	0	0
Rheumatoid arthritis	0	0	0	0
Other muscular or connective tissue disease	0	0	0	0
Specify other muscular or connec	ctive tissue disease			
		01		
		GI		
	No	Yes	Maybe	Unknown
Gallbladder disease			Maybe	Unknown
	No	Yes		
GERD/ ulcer disease	No ©	Yes	0	0
GERD/ ulcer disease Liver disease	No ©	Yes  O	0	0
GERD/ ulcer disease Liver disease	No  O	Yes  O	•	0 0
GERD/ ulcer disease  Liver disease  Other GI disease	No	Yes  O	•	0 0
Gallbladder disease  GERD/ ulcer disease  Liver disease  Other GI disease  Specify other GI disease	No	Yes  O  O  O	•	0 0
GERD/ ulcer disease  Liver disease  Other GI disease  Specify other GI disease	No  O  Bi	Yes		0 0
GERD/ ulcer disease Liver disease Other GI disease Specify other GI disease Hematologic disorder	No  O  D  No  BI	Yes	Maybe	O
GERD/ ulcer disease  Liver disease  Other GI disease	No  O  BI  No  O  O  O  O  O  O  O  O  O  O  O  O  O	Yes  O  O  Yes  O	Maybe	Unknown
GERD/ ulcer disease  Liver disease  Other GI disease  Specify other GI disease  Hematologic disorder	No  O  BI  No  O  O  O  O  O  O  O  O  O  O  O  O  O	Yes  O  O  O  O  O  O  O  O  O  O  O  O  O	Maybe	Unknown

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	No	Yes	Maybe	Unknown
Depression	0	0	•	0
Anxiety	0	0	0	0
Other mental health condition	0	0	0	0
Specify other mental health con-	dition			
	0	ther		
	No	Yes	Maybe	Unknown
Еуе	0	0	0	0
Ear, nose and throat (ENT)	0	0	0	•
Skin	0	0	0	0
Other Eye, ENT or Skin	0	0	0	0
Specify other Eye, ENT or Skin				
	Additiona	I Comments		
Clinical Diagnostic Impression				

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### **Second Examiner Opinions**

For OFFSITE exams this form is not completed.	
Choose "Save and go to Next Form" to continue.	
NO SECOND EXAMINER OPINIONS are required for this parti	cipant.
Choose "Save and go to Next Form" to continue.	•
	Form is intentionally left blank
	— Total is intentionally left blank
Reason why form was left blank	
0	
Second examiner ID number	

### FOR ALL SECOND OPINIONS

Provide initiators, qualities, radiation, severity, timing, presence after procedures done

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Coronary H	leart Dis	sease		
Congestive heart failure	O No	Yes	Maybe	Unknown
Angina pectoris	O No	Yes	Maybe	Unknown
Coronary insufficiency	O No	Yes	Maybe	Unknown
Myocardial infarct	O No	Yes	Maybe	Unknown
Provide initiators, qualities, radiation, severity, timing, presence after procedures done for Coronary Heart Disease Opinion				
Intermittent Claudication				
Intermittent claudication	O No	Yes	Maybe	Unknown
Provide initiators, qualities, radiation, severity, timing, pres Intermittent Claudication Opinion	ence after	procedure	es done for	

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	Cerebrovascular Disease
	Cerebrovascular Disease
Stroke	No Yes Maybe Unknown
ΓΙΑ	No Yes Maybe Unknown
Provide initiators, qualities, severity, timi Cerebrovascular Disease Opinion	ng, presence after procedures done for
	Additional Comments
Second Examiner Opinions	

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## **Referral Tracking**

Further Med	ical Evaluation
Was further medical evaluation recommended for this participant?	No Yes Unknown
Re	esult
Check ALL that apply	
Blood pressure - 1st BP: [sys1] / [dia1] 2nd BP: [sys2] / [dia2]	Yes

Phone call if SBP >= 200 or DBP >= 110 Expedite if SBP >= 180 or DBP >= 100 Elevated if SBP >= 140 or DBP >= 90

ECG abnormality	Yes		
Specify abnormality			
Clinic physician identified medical problem	Yes		
Specify medical problem			
Other	□ Yes		
Specify other			
Method Used to I	nform Participant		
Check ALL that apply	•		
	Yes		
Face-to-face in clinic			
Phone call			
Result letter			
Other			
Method Used to Inform Parti	cipant's Personal Physician		
Check ALL that apply			
	Yes		
Phone call			
Result letter mailed			
Result letter FAX'd - inform staff if FAX needed			
Other method - Physician			
Referral Date and Other Information			
Date referral made	Today M-D-Y		
ID number of person completing referral	$\Box$		
Notes documenting conversation with participant or participate	ant's personal physician		

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	English
For Omni participants only: Which language was primarily used in conversing with the participant?	Spanish
	Mixed
	Unknown
Additional	Comments
Referral Tracking	

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#### **LETTER TO PHYSICIAN:**

RESEARCH EXAMINATION REPORT GEN3/Omni Group 2 EXAM 3

Dear Dr. Smith:

Your patient named above participated in a research examination at the Framingham Heart Study.

Please keep in mind that the research examination at the Heart Study is not clinical care. The testing is done for research purposes only and should not be relied on to make any diagnosis, treatment, or health planning decisions. The research examination does not take place of medical care by a physician or health care provider and cannot be relied upon to identify heart or other health conditions.

Below are the blood pressure readings on your patient from the research examination. Enclosed are cholesterol/blood glucose measurements and an ECG on your patient.

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BLOOD PRESSURE:		
Systolic Blood Pressure:		
Diastolic Blood Pressure:		
We recommend that you follow up with your patient on any research findings that may be clinically significant.  Information From Medical History Interview and Routine Research Testing:		
1		
2		
3		
You may include up to ten statements.		
Some research findings may be sent in a separtate report.		
4		
5		
6		
7		
8		
9		
10		
If you have any questions, please do not hesitate to contact	me.	
Examiner		
Daniel Levy, MD Director, Framingham Heart Study		
OMB No = 0925-0216 12/31/2016		
LETTER TO RARTICIPANT		
LETTER TO PARTICIPANT:		

Dear Mr/Ms [lastname]:

Thank you again for participating in the research examination at the Framingham Heart Study. In your consent form, you gave permission to provide findings of non-genetic research tests to you and/or your physician or other health care provider. We are now providing you and your health care provider some findings as described below.

Please keep in mind that the research examination you had at the Heart Study is not clinical care and the testing is done for research purposes only and should not be relied on to make any diagnosis, treatment, or health planning decisions. The research examination does not take the place of medical care by your own physician or health care provider and cannot be relied upon to identify heart or other health conditions.

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Enclosed are some findings from the research examination a your ECG.	bout your cholesterol/blood glucose measurements and
These findings have been forwarded to your doctor or health	care provider:
PARTICIPANT'S PHYSICIAN(S) LISTED HERE	
We want to point out the following findings that we believe re	quire follow up with your health care provider:
If you have any questions, please contact Maureen Valentino, Study: 508 935 3417 / 800 536 4143.	the FHS participant coordinator at the Framingham Heart
We look forward to seeing you again and appreciate your supmakes possible our efforts to identify the cause of heart disease.	
Thank you for your continuing support.	
Examiner	
Sincerely,	
Daniel Levy, MD Director, Framingham Heart Study	
OMB No = 0925-0216 12/31/2016	
2	
3	
4	
5	
6	
7	
8	
9	
10	

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Generation 3, NOS, Omni 2

EXAM 3

## Research Center Questionnaire

#### **SECTIONS:**

Admit (pages 1 - 6) plus consents

MD (pages 7 - 112)

Self-Administered Questions (pages 113 – 142)

Tech (pages 143 - 174)

Tonometry (pages 175 - 177)

# Self-Administered Questions Section



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### **General Information (Sociodemographic)**

#### What is your current marital status?

- Single or never married
- Married or living as married or living with partner
- Separated
- Divorced
- Widowed
- Prefer not to answer

What is the HIGHEST degree or level of school you have completed? If currently enrolled, mark the highest grade completed, degree received.

- No schooling
- Grades 1-8
- Grades 9-11
- Completed high school (12th grade) or GED
- Some college but no degree

 Technical school certificate Associate degree (Junior college AA, AS) Bachelor's degree (BA, AB, BS) Graduate or professional (master's, doctorate, MD etc.) Prefer not to answer Please choose which of the following best describes your current employment status? Homemaker, not working outside the home Employed (or self-employed) full time Employed (or self-employed) part time Employed, but on leave for health reasons Employed, but temporarily away from my job Unemployed or laid off Retired from usual occupation and not working

What is your current occupation?

Unemployed due to disability

Full-time student Prefer not to answer

 Retired from usual occupation but working for pay Retired from usual occupation but volunteering

Write in occupation

From the drop down menu, please choose the code that BEST describes your occupation. Be sure to scroll down to view all choices.

- Administrative (e.g. Personnel)
- Artist/Graphic Designer/Craftsperson
- Banker/Accountant
- Clergy (Minister, Priest, Rabbi)
- Educator
- Engineer/Computer Science
- Factory/Assembly
- General Labor (e.g. Custodian, Delivery, Mailman, Truck driver)
- Heavy Labor (e.g. Construction, Landscaping)
- Homemaker
- Laboratory Technician
- Lawyer/Judge
- M.D./Dentist
- Manager/Consultant (e.g. Production Manager)
- Mechanic
- Musician

0	Nurse/Medical Personnel
	Physical/Occupational/Speech Therapist
	Police/Fire/Security/Military
	Psychologist/Social Worker/Mental Health Counselor
	Realtor
	Restaurant/Food worker
	Retail/Cashier
	Retired
	Sales/Marketing/Insurance
	Scientist/Research
	Secretary/Clerk/Data Entry
	Self Employed Business Owner
	Skilled Labor (e.g. Plumber, Carpenter, Painter Hairdresser)
	Sports Pro/Coach/Exercise Instructor
	Statistician
	Student
	Writer/Editor
	Other
Ple	ase select the income group that best represents your combined family income for the past 12 months.
0	Under \$20,000
0	\$20,000 - \$34,999
0	\$35,000 - \$54,999
0	\$55,000 - \$74,999
0	\$75,000 - \$100,000
0	Over \$100,000
	Prefer not to answer
Ηον	w many people are supported by this income?
(e.g.	1, 2, 3,)

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## **Health Insurance and Medications**

Health Insurance			
Do you currently have health insurance?			
<ul><li>No</li></ul>			
Yes			
Prefer not to answer			
Don't know			
If "Yes", check all that apply			
	Yes		
Blue Cross Blue Shield			
Harvard-Pilgrim			
Tufts			

Aetna			
Actila			
United Health Care			
Medicare			
Medicaid			
Military or Veterans Administration sponsored			
Other health insurance			
o you have prescription drug coverage?			
○ No			
○ Yes			
Prefer not to answer			
Don't know			
	Medicatio	n	
o you take any medications?			
○ No			
© Yes			
Don't know			
f "Yes"			
The questions below refer to medication	n recommended to you	u by your doctor or health	care provider.
	No	Yes	Unknown
Did you over forget to take your			Unknown
Did you ever forget to take your medicine?	0	•	Onknown
	•	0	
medicine?  Are you careless at times about			0
medicine?  Are you careless at times about taking your medicine?  When you feel better do you stop taking your medicine?  Sometimes if you feel worse	0	0	0 0
medicine?  Are you careless at times about taking your medicine?  When you feel better do you stop taking your medicine?  Sometimes if you feel worse when you take the medicine, do	0	0	0
medicine?  Are you careless at times about taking your medicine?  When you feel better do you stop taking your medicine?  Sometimes if you feel worse when you take the medicine, do you stop taking it?	0	0	0
medicine?  Are you careless at times about taking your medicine?  When you feel better do you stop taking your medicine?  Sometimes if you feel worse when you take the medicine, do you stop taking it?  How often do you forget to take your medicine?	0	0	0
medicine?  Are you careless at times about taking your medicine?  When you feel better do you stop taking your medicine?  Sometimes if you feel worse when you take the medicine, do you stop taking it?  How often do you forget to take your model.	0	0	0
medicine?  Are you careless at times about taking your medicine?  When you feel better do you stop taking your medicine?  Sometimes if you feel worse when you take the medicine, do you stop taking it?  How often do you forget to take your modern once per week	0	0	•
medicine?  Are you careless at times about taking your medicine?  When you feel better do you stop taking your medicine?  Sometimes if you feel worse when you take the medicine, do you stop taking it?  How often do you forget to take your modern than once per week  Once per week	0	0	•
medicine?  Are you careless at times about taking your medicine?  When you feel better do you stop taking your medicine?  Sometimes if you feel worse when you take the medicine, do you stop taking it?  How often do you forget to take your modern once per week  Once per week  More than once per month	0	0	•
medicine?  Are you careless at times about taking your medicine?  When you feel better do you stop taking your medicine?  Sometimes if you feel worse when you take the medicine, do you stop taking it?  How often do you forget to take your mode in the worse when you feel worse when you take the medicine, do you stop taking it?  More than once per week  Once per week  More than once per month  Once per month	0	0	•
medicine?  Are you careless at times about taking your medicine?  When you feel better do you stop taking your medicine?  Sometimes if you feel worse when you take the medicine, do you stop taking it?  How often do you forget to take your modern once per week  Once per week  More than once per month	0	0	0 0

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## Health Survey (SF-12) part 1

This questionnaire asks for your views about your health.

Please answer every question by marking one box.

If you are unsure about how to answer a question, please give the best answer you can.

- 1. In general, would you say your health is:
- Excellent
- Very Good
- Good
- Fair
- Poor

The following questions are about activities you might do during a typical day.  Does <u>your health now limit you</u> in these activities? If so, how much?
2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf
Yes, limited a lot
Yes, limited a little
No, not limited at all
3. Climbing several flights of stairs
Yes, limited a lot
<ul> <li>Yes, limited a little</li> </ul>
No, not limited at all
During the <u>past 4 weeks</u> , have you had any of the following problems with your work or other regular daily activities as a <u>result of your physical health?</u>
4. Accomplished less than you would like
• Yes
O No
5. Were limited in the kind of work or other activities
• Yes
O No
During the <u>past 4 weeks</u> , have you had any of the following problems with your work or other regular daily activities as a <u>result of any emotional problems</u> (such as feeling depressed or anxious)?
6. Accomplished less than you would like
• Yes
No
7. Didn't do work or other activities as carefully as usual
• Yes
No

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## Health Survey (SF-12) part 2

- 8. During the <u>past 4 weeks</u> how much <u>did pain interfere</u> with your normal work (including both work outside the home and housework)?
- Not at all
- A little bit
- Moderately
- Quite a bit
- Extremely

These questions are about how you feel and how things have been with you during the <u>past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm and peaceful?	0	•	•	•	•	•
10. Did you have a lot of energy?	0	0	•	•	•	•
11. Have you felt downhearted and blue?	0	0	•	0	•	•

- 12. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting friends, relatives, etc.)?
- All of the time
- Most of the time
- Some of the time
- A little of the time
- None of the time

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#### **Bleeding History**

#### Have you been diagnosed with a bleeding disorder?

- No
- Yes
- Don't know

#### If "Yes"

#### What is the name of the bleeding disorder?

- von Willebrand disease
- Hemophilia A
- Hemophilia B
- Platelet function disorder
- Immune thrombocytopenia (ITP)
- Other

If "Other" write in	
If unsure, write "unsure"	
Your age at diagnosis	
If unsure, write "unsure"	
Name of treating doctor	
If unsure, write "unsure"	-(-(-)
Name of hospital or practice and location (city,	state)
If unsure, write "unsure"	
Does <u>ANYONE</u> in your family have a history of <u>BLEE</u>	<u>DING</u> problems or complications?
For example: frequent or prolonged nosebleeds, pro	longed or excessive bleeding or bruising after cuts or trauma,
	gical procedures, heavy bleeding with periods or after delivery of a
baby	
No	
• Yes	
Don't know	
If "Yes"	
1. Please indicate if any biologically-related fan	nily members have or have had bleeding problems.
Mother	
No	
Yes	
Don't know	
Mother's side - Grandmother	
© No	
• Yes	
Don't know	
Mother's side - Grandfather	
No	
© Yes	
Don't know	

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Fat	her
0	No
0	Yes
0	Don't know
	Father's side - Grandmother
	No
	Yes
	Don't know
	Father's side - Grandfather
	No
	Yes
	Don't know
0 Di	
	indicate the <u>number</u> of biologically-related family members you have and if any of them have or have had problems.
Tota	I number of biologically-related <u>brothers</u> (WITH or WITHOUT bleeding problems)
0	No brothers
•	1 brother
	2 brothers
0	3 brothers
	4 brothers
	5 or more brothers
0	Don't know
	Total number of biologically-related <u>brothers</u> WITH bleeding problems
	No brothers
	1 brother
	2 brothers
	3 brothers
	4 brothers
	5 or more brothers
	Don't know
Tota	I number of biologically-related <u>sisters</u> (WITH or WITHOUT bleeding problems)
0	No sisters
	1 sister
	2 sisters
	3 sisters

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0	4 sisters
0	5 or more sisters
0	Don't know
	Total number of biologically-related <u>sisters</u> WITH bleeding problems
	O No sisters
	1 sister
	2 sisters
	3 sisters
	<ul><li>4 sisters</li></ul>
	5 or more sisters
	On't know
<u>Mo</u>	ther's side:
Mo	ther's side - Total number of biologically-related <u>aunts</u> (WITH or WITHOUT bleeding problems)
0	No aunts
0	1 aunt
0	2 aunts
0	3 aunts
0	4 aunts
0	5 or more aunts
0	Don't know
	Mother's side - Total number of biologically-related aunts WITH bleeding problems
	<ul><li>No aunts</li></ul>
	1 aunt
	2 aunts
	3 aunts
	<ul><li>4 aunts</li></ul>
	5 or more aunts
	On't know
Mc	other's side - Total number of biologically-related <u>uncles</u> (WITH or WITHOUT bleeding problems)
0	No uncles
0	1 uncle
0	2 uncles
0	3 uncles
0	4 uncles
0	5 or more uncles
	Don't know

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Mother's side - Total number of biologically-related uncles WITH bleeding problems	
No uncles	
1 uncle	
2 uncles	
<ul><li>3 uncles</li></ul>	
4 uncles	
5 or more uncles	
Don't know	
Father's side:	
Father's side - Total number of biologically-related aunts (WITH or WITHOUT bleeding problems)	
No aunts	
1 aunt	
2 aunts	
3 aunts	
4 aunts	
5 or more aunts	
Don't know	
Father's side - Total number of biologically-related aunts WITH bleeding problems	
No aunts	
1 aunt	
2 aunts	
<ul><li>3 aunts</li></ul>	
<ul><li>4 aunts</li></ul>	
5 or more aunts	
Don't know	
Father's side - Total number of biologically-related uncles (WITH or WITHOUT bleeding problems)	
No uncles	
1 uncle	
2 uncles	
3 uncles	
4 uncles	
5 or more uncles	
Don't know	
Father's side - Total number of biologically-related uncles WITH bleeding problems	
No uncles	
1 uncle	

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	2 uncles
	O 3 uncles
	O 4 uncles
	5 or more uncles
	O Don't know
3. Desc	ribe the type(s) of bleeding problems or bleeding complications in your family.
Write in	text
	ver required medical attention due to a nosebleed that was not associated with a trauma, or had a noseblee than 10 minutes?
O No	
Yes	
Don't kno	DW CONTRACTOR OF THE CONTRACTO
	ver experienced frequent or heavy bruising (raised bruise or a bruise greater than the size of a quarter) not trauma OR out of proportion to the size of the trauma?
O No	
Yes	
Don't kno	DW .
Have <u>YOU</u> ev tongue?	ver experienced prolonged bleeding (more than 5 minutes) when you bit yourself on the lip, cheek or
No	
Yes	
Don't kno	DW .
Have <u>YOU</u> ev	ver experienced prolonged bleeding (more than 5 minutes) with minor bodily cuts?
O No	
Yes	
Don't kno	ow .
	ter a <u>dental</u> visit, have <u>YOU</u> ever experienced prolonged bleeding that required serious medical attention cleaning <u>OR</u> tooth extraction <u>OR</u> other dental procedure?
No	
Yes	
Don't kno	DW

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lf "	res"	
	Hov	w many dental procedures (including cleaning) have you had in total (WITH or WITHOUT serious bleeding)?
	0	Less than 3 procedures
		3-10 procedures
		11 or more procedures
		Don't know
	Of t	these dental procedures, how many times did you experience a prolonged bleeding problem?
	Writ	te in a number. If unsure write "unsure"
	Wa	s a surgical procedure (e.g., stitching, restitching or packing) required to control bleeding?
	0	No
	0	Yes
		Don't know
	If "	Yes"
		Name of treating dentist:
		If unsure write "unsure"
		Name of practice and location (city, state):
		If unsure, write "unsure"
Hav	re YO	<u>U</u> ever experienced serious bleeding <u>after a surgical</u> procedure that required medical attention (for example:
		discharge, extra procedures, restitching, packing, readmission, transfusion)?
0	No	
0	Yes	
	Don'	t know
lf "	res"	
	Hov	w many total surgeries have you had (with or without serious bleeding)?
	0	1-2 surgeries
	0	3-4 surgeries
		5-6 surgeries
	0	7 or more surgeries
		Don't know

For the surgeries with the most serious bleeding, answer the following questions.

_				
Age	at surgery - surgery #1			
Write	e in age. If unsure write "unsure"			
Туре	e of surgery - surgery #1			
0	Abdominal (belly)			
0	Thoracic (heart or lungs)			
	Gynecology			
0	Throat/Nose			
0	Tonsillectomy/Adenoids			
	Other (e.g., orthopedic, spine, CNS:	central nervous system)		
	If "Other" write in - surgery #1			
	If unsure, write "unsure"			
Wer	e any action(s) taken to control th	e bleeding - surgery #1		
	No			
	Yes			
	Don't know			
	DOIT KNOW			
If "Y	es"			
		No	Yes	Don't know
	titching or surgical rgery #1	•	•	•
	od transfusion rgery #1	•	•	•
- sur Othe	rgery #1 er (clotting medication, etc.)	0	0	•
- sur Othe	rgery #1			
- sur Othe	rgery #1 er (clotting medication, etc.) rgery #1			
- sur Othe	rgery #1 er (clotting medication, etc.) rgery #1			
- sur Othe - sur	rgery #1 er (clotting medication, etc.) rgery #1 If "Other" write in - surgery #1	•	•	
- sur Othe - sur	rgery #1 er (clotting medication, etc.) rgery #1  If "Other" write in - surgery #1  If unsure, write "unsure"	R "Blood transfusion" <u>C</u>	•	
- sur Othe - sur	rgery #1 er (clotting medication, etc.) rgery #1  If "Other" write in - surgery #1  If unsure, write "unsure"  Yes" to "Restitching or surgical" O	R "Blood transfusion" <u>C</u>	•	
- sur Othe - sur	rgery #1 er (clotting medication, etc.) rgery #1  If "Other" write in - surgery #1  If unsure, write "unsure"  Yes" to "Restitching or surgical" O	R "Blood transfusion" <u>C</u>	•	
- sur Othe - sur	rgery #1 er (clotting medication, etc.) rgery #1  If "Other" write in - surgery #1  If unsure, write "unsure"  Yes" to "Restitching or surgical" O  Name of treating doctor - surgery  If unsure, write "unsure"	R "Blood transfusion" <u>C</u>	•	
- sur Othe - sur	rgery #1 er (clotting medication, etc.) rgery #1  If "Other" write in - surgery #1  If unsure, write "unsure"  Yes" to "Restitching or surgical" O	R "Blood transfusion" <u>C</u>	•	
- sur Othe - sur	rgery #1 er (clotting medication, etc.) rgery #1  If "Other" write in - surgery #1  If unsure, write "unsure"  Yes" to "Restitching or surgical" O  Name of treating doctor - surgery  If unsure, write "unsure"	R "Blood transfusion" <u>C</u>	•	

O No

Yes

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lf	"Yes"			
	Age at surgery - surgery #2			
	Write in age. If unsure write "unsure"			
	Type of surgery - surgery #2			
	<ul><li>Abdominal (belly)</li></ul>			
	<ul><li>Thoracic (heart or lungs)</li></ul>			
	Gynecology			
	Throat/Nose			
	Tonsillectomy/Adenoids			
	Other			
	If "Other" write in - surgery #2			
	If unsure, write "unsure"			
	Were any action(s) taken to control the	bleeding - surgery #2		
	No			
	Yes			
	Don't know			
	If "Yes"			
		No	Yes	Don't know
	Restitching or surgical - surgery #2	•	•	•
	Blood transfusion - surgery #2	•	•	0
	Other (clotting medication, etc.) - surgery #2	0	•	•
	If "Other" write in - surgery #2			
	If unsure, write "unsure"			
	If "Yes" to "Restitching or surgical" OF	<u>२</u> "Blood transfusion" <u>C</u>	OR "Other"	
	Name of treating doctor - surgery	#2		
	If unsure, write "unsure"			
	Name of practice and location (ci	ty, state) - surgery #2		
	If unsure, write "unsure"			

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Did you have a 3rd surgery with bleeding pr	oblems?		
○ No			
<ul><li>Yes</li></ul>			
f "Yes"			
Age at surgery - surgery #3			
Write in age. If unsure write "unsure"	<u> </u>		
Type of surgery - surgery #3			
<ul><li>Abdominal (belly)</li></ul>			
Thoracic (heart or lungs)			
Gynecology			
<ul><li>Throat/Nose</li></ul>			
<ul><li>Tonsillectomy/Adenoids</li></ul>			
Other			
If "Other" write in - surgery #3			
If unsure, write "unsure"			
Were any action(s) taken to control the	bleeding - surgery #3		
No			
© Yes			
Don't know			
20.00.00.00			
If "Yes"			
	No	Yes	Don't know
Restitching or surgical - surgery #3	•	•	0
Blood transfusion - surgery #3	0	•	•
Other (clotting medication etc.) - surgery #3	0	•	•
If "Other" write in - surgery #3			
If unsure, write "unsure"			
If "Yes" to "Restitching or surgical" OF	R "Blood transfusion" (	OR "Other"	
Name of treating doctor - surgery		<del></del>	
If upcure write ""			
If unsure, write "unsure"			

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	Name of practice and location (ci	ity, state) - surgery #3					
	If unsure, write "unsure"						
Die	Did you have a 4th surgery with bleeding problems?						
0	No						
	Yes						
lf '	'Yes"						
	Age at surgery - surgery #4						
	Write in age. If unsure write "unsure"						
	Type of surgery - surgery #4						
	, 15 do., 11 do., 1)						
	<ul><li>Thoracic (heart or lungs)</li><li>Gynecology</li></ul>						
	<ul><li>Throat/Nose</li></ul>						
	Tonsillectomy/Adenoids						
	Other						
	- Other						
	If "Other" write in - surgery #4						
	   If unsure, write "unsure"						
	Were any action(s) taken to control the	e bleeding - surgery #4					
		o blooding ourgoly # 1					
	O No						
	Yes						
	Don't know						
	If "Yes"						
	Doctitation or consider	No	Yes	Don't know			
	Restitching or surgical - surgery #4	0	0	0			
	Blood transfusion	0	0	0			
	- surgery #4						
	Other (clotting medication etc.)	•	•	•			
	- surgery #4  If "Other" write in - surgery #4						
	ii Other write iii - Surgery #4						
	If ungure write "ungure"						

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Name of treatin	g doctor - surgery #4					
	g access canger, y a					
If unsure write "u	If upgure write "upgure"					
	If unsure, write "unsure"					
Name of practic	Name of practice and location (city, state) - surgery #4					
If unsure, write "u						
Did you have a 5th surger	y with bleeding problems?					
O No						
Yes						
If "Yes"						
	70 m. 45					
Age at surgery - surg	jery #5					
Write in age. If unsure w						
Type of surgery - sur	gery #5					
<ul><li>Abdominal (belly)</li></ul>						
Thoracic (heart or	·lungs)					
Gynecology						
Throat/Nose						
Tonsillectomy/Ade	enoids					
Other						
If "Other" write	in - surgery #5					
If unsure, write "u	nsure"					
Were any action(s) to	aken to control the bleeding - surgery #5					
No						
Yes						
Don't know						
If "Yes"						
	No	Yes	Don't know			
Restitching or surgion - surgery #5	cal	•	•			
Blood transfusion - surgery #5	•	0	0			
Other (clotting medic - surgery #5	cation etc.)	•	•			

	If "Other" write in - surgery #5
	If unsure, write "unsure"
If "`	Yes" to "Restitching or surgical" <u>OR</u> "Blood transfusion" <u>OR</u> "Other"
	Name of treating doctor - surgery #5
	If unsure, write "unsure"
	Name of practice and location (city, state) - surgery #5
	If unsure, write "unsure"
	U ever been told by a doctor or healthcare provider to stop using a medication <u>because</u> you had bleeding
problem	s?
O No	
Yes	
Don't	t know
If "Yes"	
Wh	at was the name of the medication(s) you were told to stop taking due to bleeding problems?
lf ur	nsure, write "unsure"
Nar	ne(s) of treating doctor who told you to stop:
lf ur	nsure, write "unsure"
Nar	ne of hospital or practice and location (city, state):
lf ur	nsure, write "unsure"
Have YO	<u>U</u> ever <u>experienced</u> OR <u>been told</u> you have any of the following?
	n bleeding tiny purple spots particularly on the legs (petechiae)
	No
	Yes
	Don't know
If "`	Yes"
	How many times do you experience this per <i>year</i> ?
	<ul><li>Less than 1 time</li></ul>
	1-5 times
	<ul> <li>6-12 times</li> </ul>
	More than 12 times

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Spontaneous gum or mouth bleeding (do not include bleeding with tooth brushing, flossing or trauma, or gum bleeding related to gum disease)				
No				
Yes				
On't know				
If "Yes"				
How many <u>times</u> do you experien	ce this per <u>year</u> ?			
Less than 1 time				
<ul><li>1-5 times</li></ul>				
6-12 times				
More than 12 times				
Have you had excessive bleeding with your  No	period (menorrhagia)	that required medical a	ttention or treatment?	
O Yes				
Don't know				
If "Yes"				
As a result of excessive bleeding did y	you have any of the foll	owing treatments?		
As a result of excessive bleeding did y	ou have any or the fon	ownig treatments:		
	No	Yes	Don't know	
Office visit or consultation	•	•	•	
Hormonal contraception (pill or injection)	•	•	•	
Hormonal IUD (e.g., Mirena, Skyla, Liletta)	0	•	•	
Non-hormonal IUD (copper- ParaGard)	0	•	•	
Iron supplement for anemia	0	•	•	
Hysterectomy	0	•	•	
Endometrial ablation	0	•	•	
Antifibrinolytic (e.g., Amicar- aminocaproic, Lysteda- tranexamic acid)	•	0	0	
Blood transfusion (including	0	•	©	

Other

platelets or plasma only)

0

0

0

	If "Other" write in
	If unsure, write "unsure"
	What was your age when you had your first excessive bleeding problem with your period that required medical attention?
	Write in age. If unsure write "unsure"
	e you had excessive bleeding with or after the delivery of a baby requiring medical intervention (post-partum norrhage)?
0	Yes
	Don't know
	DOTT KIOW
If "Y	'es"
	How many deliveries have you had in total?
	Write in a number. If unsure write "unsure"
	How many vaginal deliveries have you had in total?
	Write in a number. If unsure write "unsure"
	How many caesarean sections have you had in total?
	Write in a number. If unsure write "unsure"
	Answer the following questions about your vaginal deliveries that had excessive bleeding requiring medical intervention.
	Was any instrumentation used in the delivery (e.g. forceps)? - delivery #1
	No
	© Yes
	O Don't know
	Age at delivery? - delivery #1
	Write in age. If unsure of age write "unsure"
	Was surgical treatment required to control the bleeding? - delivery #1
	O No
	Yes
	Don't know

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Did	you receive a blood transfusion? - delivery #1
0	No
0	Yes
0	Don't know
If "	es" to surgical treatment to control bleeding <u>OR</u> blood transfusion
	Name of treating doctor - delivery #1
	If unsure, write "unsure"
	Name of hospital or practice and location (city, state) - delivery #1
	If unsure, write "unsure"
Did you l	have a 2nd vaginal delivery with excess bleeding that required medical intervention?
No	
Yes	
Don't	know
If   \/	
If "Yes"	
Was	s any instrumentation used in the delivery (e.g. forceps)? - delivery #2
0	No
	Yes
	Don't know
Age	e at delivery? - delivery #2
Writ	e in age. If unsure of age write "unsure"
	s surgical treatment required to control the bleeding? - delivery #2
	No Yes
	Don't know
	Dont know
Did	you receive a blood transfusion? - delivery #2
0	No
0	Yes
0	Don't know
If "	Yes" to surgical treatment to control bleeding <u>OR</u> blood transfusion
	Name of treating doctor - delivery #2
	If unsure, write "unsure"

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Name of hospital or practice and location (city, state) - delivery #2
If unsure, write "unsure"
Did you have a 3rd vaginal delivery with excess bleeding that required medical intervention?
O No
© Yes
O Don't know
If "Yes"
Was any instrumentation used in the delivery (e.g. forceps)? - delivery #3
O No
Yes
On't know
Age at delivery? - delivery #3
Write in age. If unsure of age write "unsure"
Was surgical treatment required to control the bleeding? - delivery #3
No
Yes
O Don't know
Did you receive a blood transfusion? - delivery #3
O No
Yes
O Don't know
If "Yes" to surgical treatment to control bleeding <u>OR</u> blood transfusion
Name of treating doctor - delivery #3
If unsure, write "unsure"
Name of hospital or practice and location (city, state) - delivery #3
If unsure, write "unsure"
Did you have a 4th vaginal delivery with excess bleeding that required medical intervention?

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NoYesDon't know

If "Yes"		
	Was any instrumentation used in the delivery (e.g. forceps)? - delivery #4	
	O No	
	O Yes	
	On't know	
	Age at delivery? - delivery #4	
	Write in age. If unsure of age write "unsure"	
	Was surgical treatment required to control the bleeding? - delivery #4	
	O No	
	Yes	
	On't know	
	Did you receive a blood transfusion? - delivery #4	
	No	
	© Yes	
	O Don't know	
	If "Yes" to surgical treatment to control bleeding <u>OR</u> blood transfusion	
	Name of treating doctor - delivery #4	
	If unsure, write "unsure"	
	Name of hospital or practice and location (city, state) - delivery #4	
	If unsure, write "unsure"	
Dic	you have a 5th vaginal delivery with excess bleeding that required medical intervention?	
	No	
	Yes	
0	Don't know	
If "	Yes"	
••	Was any instrumentation used in the delivery (e.g. forceps)? - delivery #5	
	No No	
	O Yes	
	On't know	

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	Age at o	delivery? - delivery #5
	Write in a	age. If unsure of age write "unsure"
	Was su	urgical treatment required to control the bleeding? - delivery #5
	No	
	Yes	S
	O Dor	n't know
	Did you	u receive a blood transfusion? - delivery #5
	No	
	Yes	S
	O Dor	n't know
	If "Yes"	" to surgical treatment to control bleeding <u>OR</u> blood transfusion
	Na	ame of treating doctor - delivery #5
	lf t	unsure, write "unsure"
	Na	ame of hospital or practice and location (city, state) - delivery #5
	lf u	unsure, write "unsure"
Do	you have	e any other comments about <u>your own</u> bleeding history OR <u>your family's</u> bleeding history?

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Generation 3, NOS, Omni 2

EXAM 3

## Research Center Questionnaire

#### **SECTIONS:**

Admit (pages 1 - 6) plus consents

MD (pages 7 - 112)

Self-Administered Questions (pages 113 – 142)

Tech (pages 143 – 174)

Tonometry (pages 175 – 177)

**Tech Section** 



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### **Basic Information and Anthropometrics**

	Form is intentionally left blank
Reason why form was left blank	
Technician Number	
	Basic Information
	AL = Alabama
	AK = Alaska
	AZ = Arizona
What state do you reside in?	AR = Arkansas
Wilat State do you reside ili!	CA = California
	CO = Colorado
	CT = Connecticut

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- DC = Washington DC
- DE = Delaware
- FL = Florida
- GA = Georgia
- HI = Hawaii
- ID = Idaho
- IL = Illinois
- IN = Indiana
- IA = Iowa
- KS = Kansas
- KY = Kentucky
- LA = Louisiana
- ME = Maine
- MD = Maryland
- MA = Massachusetts
- MI = Michigan
- MN = Minnesota
- MS = Mississippi
- MO = Missouri
- MT = Montana
- NE = Nebraska
- NV = Nevada
- NH = New Hampshire
- NJ = New Jersey
- NM = New Mexico
- NY = New York
- NC = North Carolina
- ND = North Dakota
- OH = Ohio
- OK = Oklahoma
- OR = Oregon
- PA = Pennsylvania
- RI = Rhode Island
- SC = South Carolina
- SD = South Dakota
- TN = Tennessee
- TX = Texas
- UT = Utah
- VT = Vermont
- VA = Virginia
- WA = Washington

- WV = West Virginia
- WI = Wisconsin
- WY = Wyoming
- ZZ = Outside United States

If resides outside the USA, code ZZ.
If plans to wear accelerometer while visiting USA, code state of visit.

Anthropometry		
Weight	To the nearest pound, 400 = 400 or more, 888 = Refused, 999 = Not done or Unknown	
Protocol modification - Weight	Yes	
If "Yes"		
Comments protocol modification - Weight		
Height	Inches, to next lower 1/4 inch, 88.88 = Refused, 99.99 = Not done or Unknown	
Protocol modification - Height	Yes	
If "Yes"		
Comments protocol modification - Height		
Waist girth at umbilicus	Inches, to next lower 1/4 inch, 88.88 = Refused, 99.99 = Not done or Unknown	
Protocol modification - Waist girth	Yes	
If "Yes"		
Comments protocol modification - Waist girth		
Hip girth	Inches, to next lower 1/4 inch, 88.88 = Refused, 99.99 = Not done or Unknown	
Protocol modification - Hip girth	Yes	
If "Yes"		
Comments protocol modification - Hip girth		

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Additional Comments		
Basic Information and Anthropometry		



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### **Hand Grip Test**

	Form is intentionally left blank
Reason why form was left blank	
Technician Number	
Right hand	
Trial 1	Nearest kilogram, 99 = Unknown
Trial 2	Nearest kilogram, 99 = Unknown
Trial 3	Nearest kilogram, 99 = Unknown

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Left hand	
Trial 1	Nearest kilogram, 99 = Unknown
Trial 2	Nearest kilogram, 99 = Unknown
Trial 3	Nearest kilogram, 99 = Unknown
Check only if HAND GRIP test was NOT completed or NOT attempted?	■ Test NOT completed or NOT attempted
If checked	
If "Test NOT completed or NOT attempted" why not?	<ul><li>Physical limitation</li><li>Refused</li><li>Other</li><li>Unknown</li></ul>
Other reason test not done	Write in reason
Additional	Comments
Hand Grip Test	

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#### **CES-D**

	Form is intentionally left blank
Reason why form was left blank	
Technician Number	
The next questions ask about your feelings. For each statement, please say how often you felt that way	DURING THE PAST WEEK
	Rarely or none of the time (less than 1 day)
	<ul><li>Some or a little of the time (1-2 days)</li></ul>
During the past week, I was bothered by things that don't usually bother me.	<ul> <li>Occasionally or a moderate amount of the time (3-4 days)</li> </ul>
addaily bottler iller	Most or all of the time (5-7 days)

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	Rarely or none of the time (less than 1 day)
	Some or a little of the time (1-2 days)
I did not feel like eating; my appetite was poor.	<ul> <li>Occasionally or a moderate amount of the time (3-4 days)</li> </ul>
	Most or all of the time (5-7 days)
	Rarely or none of the time (less than 1 day)
	Some or a little of the time (1-2 days)
I felt that I could not shake off the blues even with the help of my family or friends.	Occasionally or a moderate amount of the time (3-4 days)
of my family of menus.	Most or all of the time (5-7 days)
	Rarely or none of the time (less than 1 day)
	Some or a little of the time (1-2 days)
I felt that I was just as good as other people.	Occasionally or a moderate amount of the time (3-4 days)
	<ul><li>Most or all of the time (5-7 days)</li></ul>
	Rarely or none of the time (less than 1 day)
	Some or a little of the time (1-2 days)
I had trouble keeping my mind on what I was doing.	Occasionally or a moderate amount of the time (3-4 days)
	Most or all of the time (5-7 days)
	Rarely or none of the time (less than 1 day)
	Some or a little of the time (1-2 days)
During the past week, I felt depressed.	Occasionally or a moderate amount of the time (3-4 days)
	Most or all of the time (5-7 days)
	Rarely or none of the time (less than 1 day)
I felt aventhing I did was an offert	Some or a little of the time (1-2 days)
I felt everything I did was an effort.	<ul> <li>Occasionally or a moderate amount of the time (3-4 days)</li> </ul>
	Most or all of the time (5-7 days)
	Rarely or none of the time (less than 1 day)
I fall have ful about the follows	Some or a little of the time (1-2 days)
I felt hopeful about the future.	Occasionally or a moderate amount of the time (3-4 days)
	Most or all of the time (5-7 days)
	Rarely or none of the time (less than 1 day)
Life county was 1850 hard because 6.22	Some or a little of the time (1-2 days)
I thought my life had been a failure.	Occasionally or a moderate amount of the time (3-4 days)
	Most or all of the time (5-7 days)

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	<ul><li>Rarely or none of the time (less than 1 day)</li><li>Some or a little of the time (1-2 days)</li></ul>
I felt fearful.	<ul><li>Occasionally or a moderate amount of the time (3-4 days)</li><li>Most or all of the time (5-7 days)</li></ul>
	Rarely or none of the time (less than 1 day)
	Some or a little of the time (1-2 days)
During the past week, my sleep was restless.	Occasionally or a moderate amount of the time (3-4 days)
	Most or all of the time (5-7 days)
	<ul> <li>Rarely or none of the time (less than 1 day)</li> </ul>
Luca harmu	Some or a little of the time (1-2 days)
I was happy.	<ul> <li>Occasionally or a moderate amount of the time (3-4 days)</li> </ul>
	Most or all of the time (5-7 days)
	Rarely or none of the time (less than 1 day)
	Some or a little of the time (1-2 days)
I talked less than usual.	<ul> <li>Occasionally or a moderate amount of the time (3-4 days)</li> </ul>
	Most or all of the time (5-7 days)
	<ul><li>Rarely or none of the time (less than 1 day)</li></ul>
	Some or a little of the time (1-2 days)
I felt lonely.	<ul> <li>Occasionally or a moderate amount of the time (3-4 days)</li> </ul>
	Most or all of the time (5-7 days)
	Rarely or none of the time (less than 1 day)
	Some or a little of the time (1-2 days)
People were unfriendly.	<ul> <li>Occasionally or a moderate amount of the time (3-4 days)</li> </ul>
	Most or all of the time (5-7 days)
	<ul><li>Rarely or none of the time (less than 1 day)</li></ul>
	<ul><li>Some or a little of the time (1-2 days)</li></ul>
l enjoyed life.	<ul> <li>Occasionally or a moderate amount of the time (3-4 days)</li> </ul>
	Most or all of the time (5-7 days)
	Rarely or none of the time (less than 1 day)
	Some or a little of the time (1-2 days)
I had crying spells.	<ul> <li>Occasionally or a moderate amount of the time (3-4 days)</li> </ul>
	Most or all of the time (5-7 days)

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	Rarely or none of the time (less than 1 day)
	Some or a little of the time (1-2 days)
I felt sad.	<ul> <li>Occasionally or a moderate amount of the time (3-4 days)</li> </ul>
	Most or all of the time (5-7 days)
	Rarely or none of the time (less than 1 day)
	Some or a little of the time (1-2 days)
I felt that people disliked me.	<ul><li>Occasionally or a moderate amount of the time (3-4 days)</li></ul>
	Most or all of the time (5-7 days)
	<ul><li>Rarely or none of the time (less than 1 day)</li></ul>
	Some or a little of the time (1-2 days)
I could not "get going".	<ul> <li>Occasionally or a moderate amount of the time (3-4 days</li> </ul>
	Most or all of the time (5-7 days)
Additio	onal Comments
CES-D	

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#### **Rosow-Breslau Questions**

		Form is intentionally left blar	ık
Reason why form was left blank			
Technician Number			
	No	Yes	Unknown
Are you able to do heavy work around the house, like shoveling snow or washing windows, walls, or floors without help?	•	•	•
Are you able to walk half a mile without help? (About 4-6 blocks)	•	•	0
Are you able to walk up and down one flight of stairs without help?	•	0	•

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Additional Comments		

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### **Physical Activity Index (PAI)**

	Form is intentionally left blank
Reason why form was left blank	
Technician Number	
Rest and Activity for a TYPICAL DAY over the PAST YEAR. A typical day = most days of the week	
SLEEP: Number of hours that you typically sleep?	99 = Unknown
SEDENTARY: Number of hours typically sitting?	99 = Unknown
SLIGHT ACTIVITY: Number of hours with activities such as standing, walking?	99 = Unknown

99 = Unknown	
99 = Unknown	
	View equation
Comment	

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#### **Physical Activity Questionnaire - Vigorous Activities**

	Form is intentionally left blank
Reason why form was left blank	
Technician Number	

Now I'll ask you about your physical activities. Only include the time spent <u>actually doing</u> the activity. For example, sitting by the pool does not count as time swimming; sitting in a chair lift does not count for skiing.

First I'll ask about <u>VIGOROUS ACTIVITIES</u>. Vigorous activities increase your heart rate, or make you sweat doing them, or make your breathe hard, or raise your body temperature. If you do an activity but not vigorously, please include it later when I ask you about other non-strenuous activities.

For all estimates, round up to nearest whole number.

In the past 12 months for at least one hour total time in any month did you do the following activities? For example, you may have done three 20 minute sessions in the month.

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In the past 12 months for at least one hour total time in any month did you do Vigorous jogging or running?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
If "Yes"	
How many months did you do this activity?	99 = Unknown
How many times per month did you do this activity?	99 = Unknown
How long did you do this activity on average each time?	Number of minutes, 999 = Unknown
In the past 12 months for at least one hour total time in any month did you do Vigorous racket sports?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
If "Yes"	
How many months did you do this activity?	99 = Unknown
How many times per month did you do this activity?	99 = Unknown
How long did you do this activity on average each time?	Number of minutes, 999 = Unknown
In the past 12 months for at least one hour total time in any month did you do Bicycle faster than 10 miles/hour or exercise hard on an exercise bicycle, elliptical, stair-master, treadmill, etc.	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
If "Yes"	
How many months did you do this activity?	99 = Unknown
How many times per month did you do this activity?	99 = Unknown
How long did you do this activity on average each time?	Number of minutes, 999 = Unknown
In the past 12 months for at least one hour total time in any month did you do Vigorous swimming?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>

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If "Yes"	
How many months did you do this activity?	99 = Unknown
How many times per month did you do this activity?	99 = Unknown
How long did you do this activity on average each time?	Number of minutes, 999 = Unknown
In the past 12 months for at least one hour total time in any month did you do Vigorous exercise class or vigorous dancing?	No Yes Unknown
If "Yes'	
How many months did you do this activity?	99 = Unknown
How many times per month did you do this activity?	99 = Unknown
How long did you do this activity on average each time?	Number of minutes, 999 = Unknown
In the past 12 months for at least one hour total time in any month did you do Any vigorous job activities such as lifting, carrying, or digging?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
If "Yes"	
How many months did you do this activity?	99 = Unknown
How many times per month did you do this activity?	99 = Unknown
How long did you do this activity on average each time?	Number of minutes, 999 = Unknown
In the past 12 months for at least one hour total time in any month did you do  Any home activities such as snow shoveling, moving heavy objects, or weight lifting (including weight training)?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
If "Yes"	
How many months did you do this activity?	99 = Unknown

How many times per month did you do this activity?	99 = Unknown
How long did you do this activity on average each time?	Number of minutes, 999 = Unknown
In the past 12 months for at least one hour total time in any month did you do Other strenuous sports such as basketball, football, skating, skiing, soccer, etc.?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
If "Yes"	
How many months did you do this activity?	99 = Unknown
How many times per month did you do this activity?	99 = Unknown
How long did you do this activity on average each time?	Number of minutes, 999 = Unknown
Additional	Comments
Physical Activity Questionnaire - Vigorous Activities	

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### **Physical Activity Questionnaire - Leisure Activities**

Reason why form was left blank  Technician Number  Leisure Activities  Now, I'd like to ask you about more LEISURE ACTIVITIES. In the past 12 months for at least one hour total time in any month did you		
Technician Number  Leisure Activities  Now, I'd like to ask you about more LEISURE ACTIVITIES. In the past 12 months for at least one hour total time in any month did you		Form is intentionally left blank
Leisure Activities  Now, I'd like to ask you about more LEISURE ACTIVITIES. In the past 12 months for at least one hour total time in any month did you	Reason why form was left blank	
Now, I'd like to ask you about more LEISURE ACTIVITIES. In the past 12 months for at least one hour total time in any month did you	Technician Number	
In the past 12 months for at least one hour total time in any month did you	Leisure A	Activities
In the west 40 menths for at least one hour total time in any	· · · · · · · · · · · · · · · · · · ·	
month did you	In the past 12 months for at least one hour total time in any month did you	- 140
Do non-strenuous sports such as softball, shooting baskets, volleyball, ping pong, or leisurely jogging, swimming or biking, which we haven't included	baskets, volleyball, ping pong, or leisurely jogging,	100

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above?

If "Yes"	
How many months did you do this activity?	99 = Unknown
How many times per month did you do this activity?	99 = Unknown
How long did you do this activity on average each time?	Number of minutes, 999 = Unknown
In the past 12 months for at least one hour total time in any month did you  Take walks or hikes or walk to work?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
If "Yes"	
How many months did you do this activity?	99 = Unknown
How many times per month did you do this activity?	99 = Unknown
How long did you do this activity on average each time?	Number of minutes, 999 = Unknown
In the past 12 months for at least one hour total time in any month did you Bowl or play golf?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
If "Yes"	
How many months did you do this activity?	99 = Unknown
How many times per month did you do this activity?	99 = Unknown
How long did you do this activity on average each time?	Number of minutes, 999 = Unknown
In the past 12 months for at least one hour total time in any month did you  Do home exercise or calisthenics?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>

If "Yes"		
How many months did you do this activity?	99 = Unknown	
How many times per month did you do this activity?	99 = Unknown	
How long did you do this activity on average each time?	Number of minutes, 999 = Unknown	
In the past 12 months for at least one hour total time in any month did you  Do home maintenance or gardening, including carpentry, painting, raking, mowing, etc.?	No Yes Unknown	
If "Yes"		
How many months did you do this activity?	99 = Unknown	
How many times per month did you do this activity?	99 = Unknown	
How long did you do this activity on average each time?	Number of minutes, 999 = Unknown	
In the past 12 months for at least one hour total time in any month did you  Do non-strenuous weight training including free weights or machines such as Nautilus?	No Yes Unknown	
If "Yes"		
How many months did you do this activity?	99 = Unknown	
How many times per month did you do this activity?	99 = Unknown	
How long did you do this activity on average each time?	Number of minutes, 999 = Unknown	
Leisure Time		
My next question is about your LEISURE TIME		
In the past week, about how many hours per day did you sit and watch TV or videos?		
In the past week, about how many hours per day did you use a computer (for leisure time) or play computer games or play video games?		

A 1 11/1 1 A		
Additional Comments		
Physical Activity Questionnaire - Leisurely Activities		

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## **Physical Activity Questionnaire - Work Activities**

	Form is intentionally left blank
Reason why form was left blank	
Technician Number	
Now, I'd like to ask you more about your physical acti In the past year	vity at WORK ONLY.
	No
Do you work?	Yes
	Unknown
If "Yes"	
In the past year	
How many hours per week do you work?	Number of hours, 999 = Unknown

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For seasonal workers - Answer for the work you do most of the year. Never Do not Often (0 hrs) Seldom **Sometimes Always** recall In the past year... 0 0 0 0 At work do you  $\mathsf{SIT}$ 0 0 At work do you STAND 0 0 0 At work do you WALK **Additional Comments Physical Activity Questionnaire - Work Activities** 

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### **Respiratory Disease**

	Form is intentionally left blank	
Reason why form was left blank		
Technician Number		
Respiratory Diagnoses		
Since your last exam ([lastexamdate])		
Have you had asthma?	No	
	Yes	
	Unknown	
If "Yes"		

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Do you still have asthma?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
Was the asthma diagnosed by a doctor or other health care professional?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
If asthma started since your last exam, at what age did it start?	Age in years, 888 = If asthma started before last exam, 999 = Unknown
If you no longer have asthma, at what age did it stop?	Age in years, 888 = Still have it, 999 = Unknown
Have you received medical treatment for this in the past 12 months?	No Yes Unknown
Have you had any of the following conditions diagnosed by	a doctor or other health care professional?
Chronic Bronchitis	No Yes Unknown
Emphysema	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
COPD (Chronic Obstructive Pulmonary Disease)	No Yes Unknown
Sleep Apnea	No Yes Unknown
Pulmonary Fibrosis	No Yes Unknown

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Additional Comments		
Respiratory Disease		

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#### **Exit Interview and Adverse Events**

	Form is intentionally left blank	
Reason why form was left blank		
Technician Number		
Exit Interview		
	No	
	Yes	
Removed and placed bar code label in chart?	Bar code label not used	
	Unknown	
	No	
Referral sheet reviewed?	Yes	
	Unknown	

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Dietary questionnaire brought to Research Center?	<ul><li>No (refused or forgot to bring at time of exam)</li><li>Yes</li><li>Sent home</li><li>Unknown</li></ul>
Left center with medications and belongings?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>
Left center with accelerometer?	<ul><li>No, refused</li><li>Yes</li><li>Mailed to participant</li><li>Unknown</li></ul>
Left center with stool microbiome kit?	<ul><li>No, refused</li><li>Yes</li><li>Mail</li><li>Unknown</li></ul>
If "Yes" or "Mail"	
Microbiome id number	
<u>IPHONE</u> - Left center with eFHS app?	<ul><li>No, refused</li><li>No, no iPhone</li><li>Yes</li><li>Will return later for set up</li><li>Unknown</li></ul>
ANDROID - Left center with eFHS app?	<ul> <li>No, refused</li> <li>No, no Android</li> <li>Yes</li> <li>Will return later for set up</li> <li>Unknown</li> </ul>
Left center with TBI survey information?	<ul><li>No, refused</li><li>Yes</li><li>Unknown</li></ul>

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Feedback Check all that apply and supply comments		
Feedback - NONE		
Feedback - POSITIVE		
Feedback - NEGATIVE		
Feedback - OTHER		

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# Adverse Events (not requiring further medical evaluation)

Technician Number		
Was there an adverse event in clinic that does not require further medical evaluation?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>	
Adverse Event comments		
Technician who reviewed that all REDCap form questions were completed		
Additional Comments		
Exit Interview and Adverse Events		

Your exam today was for research purposes only and is not designed to make a medical diagnosis.

The exam cannot identify all serious heart and health issues.

It is important that you continue regular follow-up with your physician or your health care provider.

Generation 3, NOS, Omni 2

EXAM 3

## Research Center Questionnaire

#### **SECTIONS**:

Admit (pages 1 - 6) plus consents

MD (pages 7 - 112)

Self-Administered Questions (pages 113 – 142)

Tech (pages 143 - 174)

Tonometry (pages 175 - 177)

**Tonometry Section** 



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### **Tonometry Worksheet**

Tonometry Work	Tonometry Worksheet Questions		
Have you had any caffeinated drinks in the last 6 hours?	No Yes Unknown		
If "Yes"			
How many cups?	99 = Unknown		
Have you eaten anything else including fat free pretzels this morning?	No Yes Unknown		

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Have you smoked cigarettes in the last 6 hours?	<ul><li>No</li><li>Yes</li><li>Unknown</li></ul>	
If "Yes"		
	Example: 6 1/2 hours = 6 hours, 30 minutes	
How many hours since your last cigarette? - hour portion	99 = Unknown	
How many minutes since your last cigarette? - minute portion	99 = Unknown	
Tonometry Test Status		
Tonometry Sonographer ID		
Date of tonometry scan?	Today M-D-Y	
Was tonometry done?	<ul> <li>No, test was not attempted or done</li> <li>Yes, test was done, even if all 4 pulses could not be acquired and recorded</li> </ul>	
If "No"		
Reason why (check all that apply):		
Subject refusal	Yes	
Subject discomfort	Yes	
Time constraint	Yes	
Equipment problem	Yes	
If "Yes"		
Specify equipment problem		
Other	Yes	
If "Yes"		
Specify other problem		

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#### **Additional Comments**

Tonometry Worksheet						