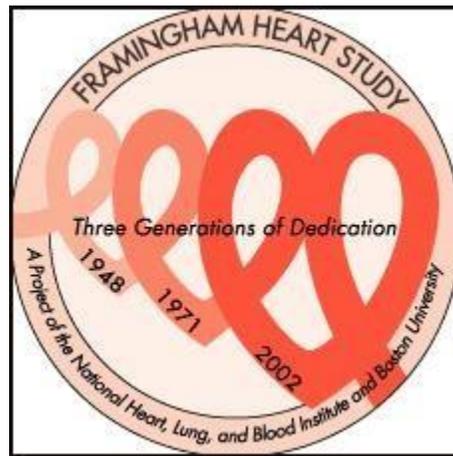


Dataset: e_exam_ex03_3b_1069s

Note: Spanish version of clinic exam data collection form is included in this protocol document.



FRAMINGHAM HEART STUDY

Generation 3, Omni 2, NOS Exam 3

CLINIC PROTOCOL MANUAL

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Framingham Heart Study
Group 3 Exam 3
RESEARCH CONSENT FORM

Welcome Back to the Framingham Heart Study

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

Why is the research study being done?

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

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

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

About your consent

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

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

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

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

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

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



THE FRAMINGHAM HEART STUDY

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What will happen in this research exam?

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

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

As before, we will

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

Surveys

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

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

There are some new research activities.

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

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

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

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

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

What risks can I expect? Having bone density tests involve the use of x-rays, which are a form of radiation. The amount of radiation that you will be exposed to as part of this study is less than a third of the radiation you would receive from a chest x-ray. The radiation exposure from these tests is so small that there is no significant risk to your health.

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

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

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

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

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

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

5. Nose Swab: We will collect cells by gently brushing the inside of your nose. The cells will be used to examine how changes in DNA, RNA and DNA methylation are related to lung function and lung diseases and other diseases.

What risks can I expect? *Brushing inside your nose using a soft brush can cause mild to moderate discomfort. There may be a small amount of bleeding. If bleeding does occur, gentle pressure can be used to stop the bleeding.*

If you are taking medications to thin the blood (anti-coagulants) or if there are any signs of bruising inside your nose or other causes that may make it too difficult to collect cells from your nose, we will not complete the test. .

6. 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:

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

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



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

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

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

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

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

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

Genetic Studies

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

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

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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

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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, nose cells, 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

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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.

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Patenting Discoveries

Research from this study may, one day, result in new tests to diagnose or predict diseases. It may also lead to the development of new 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.



THE FRAMINGHAM HEART STUDY

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

1) | YES | NO (Office Code 0)

I agree to participate in the FHS examination, including the collection of data, blood, urine samples, and nose cells, 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.

2) | YES | NO (Office Code 13)

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.

3) | YES | NO (Office Code 3)

I agree to allow my data, blood, DNA and other genetic material, iPS cells and their derivatives, urine samples, nose cells, 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.

4) | YES | NO (Office Code 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, nose cells, and any other specimens for research. I understand that my data and specimens will be shared without my name or direct personal identifiers.

5) | YES | NO (Office Code 30)

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.

6) | YES | NO (Office Code 31)

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.



THE FRAMINGHAM HEART STUDY

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

Participant's Signature	Printed Name	Date
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Legally Authorized Representative (LAR)'s Signature	Printed Name	Date
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Person Obtaining Consent Signature	Printed Name	Date
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A05 Exam Consent Form Span

FHS_IDTYPE_ID _____

Name: [firstname] [lastname] FHS ID: [fhs_idtype_id]**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 Cardíaco, 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 vasan@bu.edu 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 está 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.

BU/BMC Institutional Review Board
IRB NUMBER: H-32132
IRB APPROVAL DATE: 09/01/2016
Res.v17

Name: [firstname] [lastname] FHS ID: [fhs_idtype_id]

¿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.

Hay algunas nuevas actividades de investigación.

1. Evaluación del estado cardio-pulmonar: La evaluación de su condición cardiopulmonar 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 cardíaca. 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.

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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.

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. FibroScan: 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 Medicare 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.

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.

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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. Acelerómetro: 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.

Riesgos Desconocidos: Existe la posibilidad de otros riesgos que no hemos identificado hasta el momento.

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.

¿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.

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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 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.

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¿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 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 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.

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Tomar parte en este estudio depende solo de usted. Si decide tomar parte ahora, 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.

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.
(code0)

Si No

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.
(code13)

Si No

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.
(code3)

Si No

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.
(code4)

Si No

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.
(code30)

Si No

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.
(code31)

Si No

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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

(Firma del participante)

Fecha

Firma del representante legal autorizado (LAR)

(Firma del LAR)

Fecha (LAR)

Firma de la persona que obtiene el consentimiento

(Use dropdown for your Tech ID)

Fecha (Witness)

Comentarios sobre los consentimientos

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March 22, 2016

John Doe
Apt 1234
305 West 777th St.
New York, NY 10024

Id: 3 - 1234

Dear Mr. Doe,

We thank you for participating in the Framingham Heart Study. Your clinic appointment is scheduled for Friday, March 18, 2016 at 7:30 am.

The Framingham Heart Study's address is 73 Mt. Wayte Avenue, in the Perini Building. There is reserved parking for participants behind the Franklin Street wing. Please see the enclosed map. The building is handicap accessible.

You should bring walking shoes, loose fitting shorts, and if you choose, slippers and your own robe. In order to perform certain tests, we ask that you **NOT** eat after 7:00 P.M. the previous evening. You may have **water, decaffeinated black coffee or tea (no creamer, milk or sugar).**

Do not exercise 4 hours before the exam.

A urine sample will be collected when you arrive.

Please do not wear jewelry because of the Bone Density Scan.

Please take any prescription medications, as you normally would.

Using the enclosed **MEDICATION BAG**, please bring all prescription and nonprescription medications **you currently take or have taken in the past month** in their original containers.

ON THE BACK OF THIS SHEET, please list information regarding hospitalizations and major illnesses you have experienced since your last exam or health history with the Framingham Heart Study.

If you would like to review the consent form in advance please go to www.framinghamheartstudy.org and click on Exam 3 Consent form. Please call Maureen Valentino at the number below if you would like the consent mailed.

PLEASE BRING THIS LETTER WITH YOU TO THE CENTER. If you need help completing this form, the staff can assist you at the time of your appointment. If you have any questions, please call Maureen Valentino, Participant Coordinator at **(508) 935-3417** locally and for long distance at **(800) 536-4143**.

Sincerely yours,



Daniel Levy, MD

Director

Framingham Heart Study
OMB No=0925-0216

OVER →

Doctor(s)/Health Care Provider you want your report sent to:

Name	Address	Telephone
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Hospitalizations, Emergency Room Visits, or Day Surgeries since 01/18/2016:

Date	Reason	Hospital Name & Address	Doctor's Name
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Doctor's Office Visits:

Date	Reason	Doctor's Name
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Framingham Heart Study Pregnancy Screening Protocol

(To be used in conjunction with script and Pregnancy Determination form for all female participants)

1. Using the IRB approved telephone script, call participant to set up appointment or to remind her of the scheduled exam.
2. Advise the participant that pregnant women or women trying to become pregnant should not have the research test.
3. Complete pregnancy screening using the pregnancy determination form.
4. Notify women of childbearing potential (who are neither pregnant nor trying to become pregnant) that a pregnancy test will be required before the research test and that if the pregnancy test is positive she will not be able to have the research test at that time.
5. Ask the participant to cancel the scheduled appointment if she thinks she may be pregnant.
6. File pregnancy determination form in the participant's chart.
7. On the day of the exam, check responses on pregnancy determination form with participant. If the research test is part of an ancillary study, make a copy of the pregnancy determination form and give it to the ancillary study coordinator for their records.
8. Advise participants who require pregnancy test that pregnancy tests are not always accurate. (They can produce false negative results.) Therefore, if the participant thinks she may be pregnant or if she is trying to conceive, she should not have the test.
9. Complete the pregnancy test.
10. If the test is positive, give the participant the result and let her know that she cannot complete the test while pregnant.
11. If the test is negative and the participant has no reason to believe she may be pregnant, she may have the test.

Pregnancy Screening Telephone Script

(Use when setting up appointment or at time of reminder call for FHS core exam)

“Hello my name is _____. I am calling from the Framingham Heart Study to schedule your appointment / or to remind you of your appointment for the ___ test/FHS Clinic Exam. Women who are pregnant or trying to become pregnant should not have this test to avoid any potential risk to the fetus (unborn child). Therefore, we need to ask you a few questions to be sure that you are not pregnant. “

(Refer to pregnancy determination form.)

If applicable:

“On the day of the test we will complete a pregnancy test. If the test is positive, you will not be able to have the test at this time.

Pregnancy tests are not always accurate. Therefore, if you think you may be pregnant or if you are trying to conceive, please call to cancel the appointment and/or to let us know, as pregnant women should not have this test.

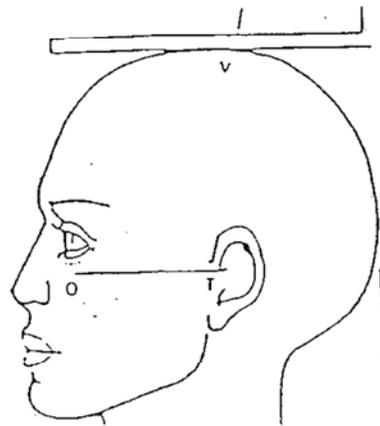
Thank you very much for participating in the Framingham Heart Study. Please do not hesitate to call us if you have any questions regarding the test, or if you are unsure about any of the details that we have just discussed.”

Standing Height Measurement Protocol

1. Participant should be barefoot or wearing thin socks. Ask participant to stand erect with his/her back to vertical mounted stadiometer.
2. Heels should be together and against the vertical ruler, both feet flat on the floor, with weight distributed evenly across both feet. Check to make sure both feet are back against the wall.
3. Participant faces straight ahead with his/her head positioned in the Frankforhorizontal plane (see next page). The lower margin of the bony orbit (the socket containing the eye) should be on the same horizontal plane as the most forward point in the supratragal notch (the notch just above the anterior cartilaginous projections of the external ear).
4. Ask participant to let arms hang freely by the sides of the trunk, palms facing the thighs. Ask participant to inhale deeply and maintain a fully erect position.
5. Bring the level down snugly (but not tightly) on top of participant's head.
6. Record measurement to the **nearest 1/4 inch, rounding down.**

Standing Height Measurement

FRANFORT PLANE FOR MEASURING BODY HEIGHT



- ORBITALE: Lower margin of eye socket
- TRAGION: Notch above tragus of ear or at upper margin of zygomatic bone at that point
- FRANFORT PLANE: Orbitale-tragion horizontal line

Weight Measurement Protocol

1. Ask participant to wear FHS gown for measurement if he/she brought a heavy gown from home ask them to remove it. The participant should remove slippers or shoes.
2. Prior to asking participant to step onto the scale, lift the counter poise and position it at zero.
3. Ask the participant to step onto the scale, facing measurement beam.
4. Instruct the participant to stand in the middle of the scale platform with head erect and eyes looking straight ahead. Weight should be equally distributed on both feet and the participant should not touch or support him/herself.
5. With the participant standing still in the proper position lift the counterweight (larger weight) and slide it to the right until the beam approaches balance.
6. Adjust the top poise until the beam is evenly balanced.
7. Have the participant step off the scale. The technician should stand directly in front of the scale and read the weight with eyes level to the point of measurement.
8. Record the weight to the nearest pound; **round up if ≥ 0.5 , round down if < 0.5 .**
9. If deviations from the protocol occur record it as a protocol modification.

Equipment and Calibration For Height and Weight

1. Scale to measure body weight in lbs.:
 Worcester Scale Co., Inc.
 228 Brooks Street
 Worcester, MA
 508-853-2886

2. Weights to calibrate scale: One 50 lb weight and two 25 lb weights
 Worcester Scale Co., Inc. (See address above)

3. Accu Hite Stadiometer
 Quick Medical
 425-831-5963
 888-345-4858

Annual/Monthly/Daily Height and Weight Equipment Calibration Protocol

<u>Activity</u>	<u>Daily</u>	<u>Weekly</u>	<u>Monthly</u>	<u>Yearly</u>
Scale				
Zero Reading	X			
50# Weight			X	
Professionally Calibrated				X
Stadiometer				
Check Level			X	

1. Scales: **Annually/Monthly/Daily (during clinic)**

Protocol:

Daily:

- a. To balance scale, move both poises to zero. If not balanced, turn balance screw to right or left until scale balances.

Monthly:

- b. Once a month scales are to be calibrated.
- c. Set both poises at zero
- d. Place a 50 lb weight onto the scale.
- e. Set bottom poise to 50 (top poise at 0).
- f. If scale is balanced then calibration is done.
- g. If not balanced, turn balance screw to right or left until scale balances.
- h. Set top poise to 50 (bottom poise at 0)
- i. If scale is balanced then calibration is done.
- j. If not balanced, turn balance screw to right or left until scale balances..
- k. Mark the date in the calibration log book located in the clinic office.
- l. Scales must be certified on a yearly basis. This information can be found in the Clinic Equipment Book located in the clinic office.

2. Stadiometers: **Monthly**

Protocol:

- a. Using the purple measuring tape located in the Center Float Desk drawer.
- b. Line up against the meter to determine correct marker points.
- c. Make sure to move up and down at different spots along the meter.
- d. If lines do not match up then a new stadiometer must be ordered.
- e. Check the Level in the end of the sliding piece.
- f. If level is uneven then it needs to be adjusted.
- g. Mark date in calibration log book once a month.

**SCALE and STADIOMETER
Monthly Calibration Log
Room #**

Year \	JAN.	FEB.	MARCH	APRIL	MAY	JUNE
Stadiometer						
Scale						

Year \	JULY	AUG	SEPT	OCT	NOV	DEC
Stadiometer						
Scale						

Training and Certification of Staff

New Staff

- Given Protocol to read, understand, ask questions to Supervisor
- Protocol is demonstrated by Supervisor
- New Staff observes other Techs performing Protocol
- New Staff practices Protocol on staff and volunteers
- New Staff performs Protocol on participant with Supervisor or Certified Tech observing
- When Supervisor feels New Staff is proficient in Protocol, Supervisor will certify New Staff
- Certified New Staff will perform Protocol on own
- Certification date is noted in Certification Log

Recertification of Staff

- Occurs when there is a major deviation on Supervisor Observations or a new study with a new protocol is introduced into the exam
- Protocol is demonstrated by Supervisor
- Staff observes other Techs performing Protocol
- When Supervisor feels Staff is proficient in Protocol, Supervisor will recertify Staff
- Recertification date is noted in Certification Log

Quality Control

In order to maintain the quality of the data, every 6 weeks, each technician that performs anthropometric measures must complete quality control measurements.

This is done for:

- 1) Waist and Hip
- 2) Height and Weight

Height and Weight

Each technician, paired with another technician and out of each other's view, performs each height and weight measurement.

Height: Record in inches rounded down to the nearest $\frac{1}{4}$ inch

Weight: Record in whole pounds recorded to nearest pound. Round up if ≥ 0.5 , round down if < 0.5

If the difference in height is more than .25 inches, the measurement is repeated.

If the difference in weight is more than 1 pound, or the average of .5 pound, the measurement is repeated.

Supervisor Observations performed quarterly

QC Reports with summary of measurements done by technician prepared quarterly by Data Management

Date: _____

Tech ID# _____

Supervisor: _____

Participant _____

**Standing Height Measurement
Supervisor Checklist**

Check that each procedure is carried out correctly. Check yes if correct or no if incorrect. Provide an explanation of the incorrect item. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the exam.

Yes	No	Standing Height Measurement
		The participant should be barefoot or wearing thin socks so positioning of the body can be seen. Ask participant to stand erect with his/her back to vertical mounted stadiometer.
		Heels should be together and against the vertical ruler, both feet flat on the floor, with weight distributed evenly across both feet. Check to make sure both feet are back against the wall.
		Participant faces straight ahead with his/her head positioned in the Frankfort horizontal plane. The lower margin of the bony orbit (the socket containing the eye) should be on the same horizontal plane as the most forward point in the supratragal notch (the notch just above the anterior cartilaginous projections of the external ear).
		Ask participant to let arms hang freely by the sides of the trunk, palms facing the thighs. Ask participant to inhale deeply and maintain a fully erect position.
		Bring the level down snugly (but not tightly) on top of participant's head. Use an extension board for proper measurement of severely kyphotic subjects.
		Record measurement to the nearest 1/4 inch, rounding down.

Yes	No	Deviations
		Did the tech perform any minor deviations?
		Did the tech perform any major deviations?
Comments/Corrections/Deviations:		
Supervisor Initials:		
Date:		

Date: _____

Tech ID# _____

Supervisor: _____

Participant _____

**Weight Measurement
Supervisor Checklist
Clinic**

Check that each procedure is carried out correctly. Check yes if correct or no if incorrect. Provide an explanation of the incorrect item. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the exam.

Yes	No	Weight Measurement
		Ask participant to wear FHS gown for measurement if he/she brought a heavy gown from home. The participant should remove slippers or shoes.
		Prior to asking the participant to step onto the scale, lift the counter poise and position it at zero.
		Ask the participant to step onto the scale, facing measurement beam.
		Instruct the participant to stand in the middle of the scale platform with head erect and eyes looking straight ahead. Weight should be equally distributed on both feet, and participant should not touch or support him/herself.
		With the participant standing still in the proper position, lift the counterweight (larger weight), and slide it to the right until the beam approaches balance.
		Adjust the top poise until the beam is evenly balanced.
		Have the participant step off the scale. The technician should stand directly in front of the scale and read the weight with eyes level to the point of measurement.
		Record the weight to the nearest pound; round up if ≥ 0.5, round down if < 0.5.

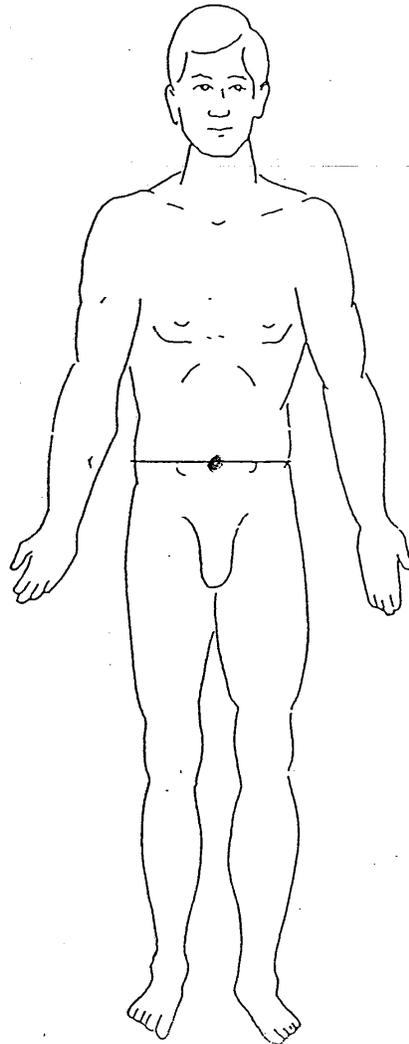
Yes	No	Deviations
		Did the tech perform any minor deviations?
		Did the tech perform any major deviations?
Comments/Corrections/Deviations:		
Supervisor Initials		
Date:		

Waist Girth at Umbilicus

1. Participant stands erect, arms hanging loosely at sides, feet together and weight equally distributed on both feet, facing straight ahead. The technician will take the gown from the back and place it over the left shoulder of the participant. The technician will ask the participant to cross their arms over their chest with hands at shoulders and hold the gown in place
2. Apply anthropometric tape at the level of the umbilicus. Roll underpants down below umbilicus if underwear is covering umbilicus.
3. Apply tape snugly but not tightly.
4. Make sure the tape is horizontal and not twisted, checking from both the front and back by using 2 mirrors mounted to the wall.
5. Before recording measurement ask the participant to fully relax their shoulders.
6. Record measurement **to the nearest 1/4 inch, rounding down.**

--

Waist Girth

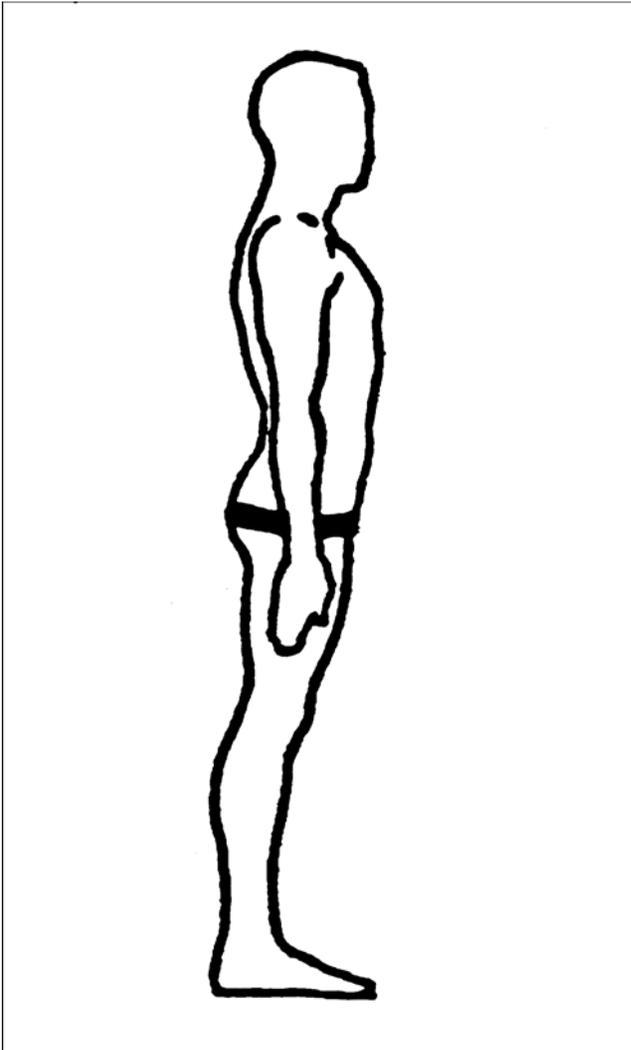


Waist Girth at level
of umbilicus.

Hip Circumference Measurement

1. Participant stands erect, arms hanging loosely at sides, feet together and weight equally distributed on both feet, facing straight ahead. The technician will take the gown from the back and place it over the left shoulder of the participant. The technician will ask the participant to cross their arms over their chest with hands at shoulders and hold the gown in place.
2. The examiner stands on the participants left side and applies the measuring tape around the maximum extension of the buttocks (see figure on next page).
3. The examiner should be squatting or kneeling so that their eyes are at the level of the maximum extension of the buttocks.
4. Make sure the tape is horizontal and not twisted, checking from both the front and back by using 2 mirrors mounted on the wall.
5. The zero end of the tape is held under the measurement value.
6. Apply tape snugly but not tightly.
7. Record measurement **to the nearest ¼ inch, rounding down.**
8. If the participant is wearing baggy underpants then the examiner stands in back and gathers the side seams together and places the thumb in the fabric to make a fold.





Date: _____ Tech ID# _____ Quarter: I, II, III, IV (circle one)
 Supervisor: Emily Manders Participant Label _____

Anthropometrics

Check that each procedure is carried out correctly. Check yes if correct or no if incorrect. Provide an explanation of the incorrect item. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the exam.

	No	Hip Circumference
		Participant stands erect, arms hanging loosely at sides, feet together and weight equally distributed on both feet, facing straight ahead. The examiner tells the participant that she is going to open the robe and place it over the ppt left shoulder. The examiner then asks the ppt to cross arms over chest to hold the robe, standing up straight but shoulders relaxed, weight equally distributed on both feet, facing straight ahead
		The examiner stands on the participants left side and applies the measuring tape around the largest part of the buttocks.
		The examiner then adjusts the sides of the tape and checks the front and sides of the tape measure is horizontal
		The zero end of the tape is held under the measurement value
		Apply tape snugly but not tightly
		Record measurement to the nearest ¼ inch, rounding down

Yes	No	Waist Girth Measurement
		Participant is asked to stand erect with head facing straight ahead. The examiner tells the participant that she is going to open the robe and place it over the ppt left shoulder. The examiner then asks the ppt to cross arms over chest to hold the robe, standing up straight but shoulders relaxed.
		The examiner places the anthropometric tape at the level of the umbilicus, underneath the gown. If underwear is covering the umbilicus, the examiner rolls down the under below the umbilicus.
		Tape is applied snugly but not tightly.
		The examiner checks the tape that it is placed horizontal and not twisted. It is checked from both the front and back using 2 mirrors mounted to the wall.

Date: _____ Tech ID# _____ Quarter: I, II, III, IV (circle one)
 Supervisor: Emily Manders Participant Label _____

		Measurement is recorded to the nearest ¼ inch, rounding down.
--	--	---

Yes	No	Deviations
		Did the tech perform any minor deviations?
		Did the tech perform any major deviations?
Comments/Corrections/Deviations:		
Supervisor Initials:		
Date:		

Tech1 Measurement Page

Record ID _____

FHS_IDTYPE_ID (double check) _____
(for example 3-0009 or 3-1234)

Tech1 ID Number _____

Measurement Date _____

Intertech QC Measurements - Height and Weight

Each tech paired with another tech and out of each other's view, performs each height and weight measurement.
If the difference in height is more than .25 inches, the measurement is repeated by tech2.
If the difference in weight is more than 1 pound, the measurement is repeated by tech2.

Height Measurement (rounded down to nearest 1/4 inch) _____

Repeated Height Measurement _____

Weight Measurement (recorded to nearest pound) _____
(round up if ≥ 0.5 , round down if < 0.5)

Repeated Weight Measurement _____

Intertech QC Measurements - Waist and Hip

Each tech paired with another tech and out of each other's view performs each measurement.
Measurements with a difference of $> .50$ in. on the umbilicus waist measurement are repeated.
Measurements with a difference of $> .50$ in. on the hip (Buttocks) Circumference are repeated.

Umbilicus Waist Measurement (inches) _____
(to next lower 1/4 inch)

Repeated Umbilicus Waist Measurement _____

Hip Circumference (inches) _____
(to next lower 1/4 inch)

Repeated Hip Circumference _____

Tech2 Measurement Page

Record ID _____

FHS_IDTYPE_ID: [idtype_id_tech1]

Tech2 ID Number _____

Measurement Date _____

Intertech QC Measurements - Height and Weight

Each tech paired with another tech and out of each other's view, performs each height and weight measurement. If the difference in height is more than .25 inches, the measurement is repeated by tech2. If the difference in weight is more than 1 pound, the measurement is repeated by tech2.

Height Measurement (rounded down to nearest 1/4 inch) _____

Repeated Height Measurement _____

Weight Measurement (recorded to nearest pound) _____
(round up if ≥ 0.5 , round down if < 0.5)

Repeated Weight Measurement _____

Intertech QC Measurements - Waist and Hip Circumference

Each tech paired with another tech and out of each other's view performs each measurement. Measurements with a difference of $> .50$ in. on the umbilicus waist measurement are repeated by tech2. Measurements with a difference of $> .50$ in. on the hip (Buttocks) Circumference are repeated by tech2.

Umbilicus Waist Measurement (inches) _____
(to next lower 1/4 inch)

Repeated Umbilicus Waist Measurement _____

Hip Circumference (inches) _____
(to next lower 1/4 inch)

Repeated Hip Circumference _____

ComparisonPage

Record ID _____

Comparison after Tech 2 Measures

Difference between heights (inches)

(should be ≤ 0.25 inch)Alert! Difference between heights is > 0.25 inch.
Click YES. Tech2 repeats the measurement.

- Yes
 No

Difference between weights (pounds)

(should be ≤ 1 lb)Alert! Difference between weights is > 1 lb. Click
YES. Tech2 repeats the measurement.

- Yes
 No

Difference between waist measurement (inches)

(should be ≤ 0.5 inch)Alert! Difference between waist measurements is > 0.50 inch. Click YES. Tech2 repeats the measurement.

- Yes
 No

Difference between hip measurements (inches)

(should be ≤ 0.5 inch)Alert! Difference between hip measurements is > 0.50 inch. Click YES. Tech2 repeats the measurement.

- Yes
 No

Comparison After Tech 2 Repeats Measurements

Alert! Difference between heights is still > 0.25 inch. Click YES. Tech1 repeats the measurement.

- Yes
 No

Alert! Difference between weights is still > 1 lb.
Click YES. Tech1 repeats the measurement.

- Yes
 No

Alert! Difference between waist measurements is still > 0.50 inch. Click YES. Tech1 repeats the measurement.

- Yes
 No

Alert! Difference between hip measurements is still > 0.50 inch. Click YES. Tech1 repeats the measurement.

- Yes
 No

SIX WEEK CYCLE QUALITY CONTROL TRACKING FORM

_____8/15/2016- 09/26/2016_____

TECH ID	HEIGHT/WEIGHT	WAIST	HIP
788/19			
788/865			
788/794			

TECH ID	HEIGHT/WEIGHT	WAIST	HIP
19/788			
19/865			
19/794			

TECH ID	HEIGHT/WEIGHT	WAIST	HIP
865/19			
865/788			
865/794			

TECH ID	HEIGHT/WEIGHT	WAIST	HIP
794/19			
794/788			
794/865			

MONTHLY/ANNUALLY CALIBRATIONS-2016-2017

Year Month	SEPT	OCT	NOV	DEC	JAN 2017	FEB
Room 102 (ECG)						
Stadiometer Level Scale						
Measuring Tape Hand Grip						
Room 103 (ECG)						
Stadiometer Level Scale						
Measuring Tape Hand Grip						
Room 114 (ECG)						
Stadiometer Level Scale						
Measuring Tape Hand Grip						
Room 109 (MD)						
Manometer						
Room 107 (MD)						
Manometer						

	SEPT	OCT	NOV	DEC	JAN 2017	FEB 2017
Room 102 (ECG)						
Stadiometer Level						
Scale						
Measuring Tape						
Hand Grip						
Room 103 (ECG)						
Stadiometer Level						
Scale						
Measuring Tape						
Hand Grip						
Room 114 (ECG)						
Stadiometer Level						
Scale						
Measuring Tape						
Hand Grip						
Room 109 (MD)						
Manometer						
Room 107 (MD)						
Manometer						

CES-D Scale

A. Rationale and Background:

The Center for Epidemiologic Studies Depression Scale (CES-D) was developed for use in epidemiologic research of depressive symptomatology in the general population. It was designed as a screening instrument to elicit symptoms associated with depression. It is intended to document the presence and severity of depressive symptoms but is not intended to make clinical diagnosis. It assesses the current state of the subject by focusing on symptomatology in the past week.

Note: The depression questions used in the NHANES 1 survey were the 20-item set of the CES-D developed and validated by the Center for Epidemiologic Studies, National Institute of Mental Health (NIMH).

The scale is given at each exam. The scale is not given if the patient is: sedated, aphasic, non-English speaking, or uncooperative.

B. Procedure:

1. Each question is read to the participant who responds with one of four answers.
2. Response alternatives should be printed on paper which is placed in front of the participant for reference.
3. Each category of response should be explained to the participant prior to administering the scale.
4. If the participant is unable to read the response sheets, the interviewer should read each response as well as the question referring to their feelings in the past week.
5. Be sure the participant understands that the questions refer to his/her feelings only during the past week.

C. CES-D Scoring:

Each item has a range of four response options which indicated how often the survey examinee had felt that way during the past week:

Response Option

Rarely or none of the time (less than 1 day)

Some or a little of the time (1-2 days)

Occasionally or a moderate amount of the time (3-4 days)

Most or all of the time (5-7 days)

Questionnaire items 4, 8, 12, and 16 were worded in a positive (i.e., nondepressed) direction. The other 16 scale items were worded in a negative direction to elicit depressive symptomatology directly. To score the CES-D, the sense of the four positive questionnaire items was reversed by subtracting their coded value (indicating the response option selected) from 3. Then the coded values for all 20 items were summed into a total score. The range of possible scores was 0-60. The final score is calculated by the computer.

D. Methods:

The CES-D Questionnaire consists of 20 questions. Since it is a scale for depression, it must be completed using responses by the participant, not a proxy.

SCRIPT: *The questions below ask about your feelings. For each of the following statements, please say if you felt that way during the past week.*

1. Hand the response sheet to the participant and explain the response options. The following definitions should be given:

Code

Rarely or none of the time (< one full day)

Some or a little of the time (1 to 2 days in the past week)

Occasionally or moderate amount of time (3 to 4 days in the past week, or about 1/2 the time)

Most of the time (5 to 7 days in the past week)

If participant answers *YES* to a given statement, repeat the above responses to get a correct answer.

2. Read each item as it is written on the form. Preface statements 1, 6 & 11 with the statement *During the past week*, then continuing with the response categories. For example:

SCRIPT: *During the past week I was bothered by things that usually don't bother me. Did you feel that way rarely or none of the time, some or a little of the time, occasionally or moderate amount of time, or most or all of the time?*

Question 1: During the past week I was bothered by things that usually don't bother me.

Question 6: During the past week I felt depressed.

Question 11: During the past week my sleep was restless

****Note: Emphasize to the participant that it is only the past 7 days.****

3. Discontinue reading the responses when the participant provides a response before you are finished. On the next item, however, again begin to read the entire set of responses.
4. Code **9** = *Refused* or *Do not know* is used when:
 - a. The question was asked, but the participant chooses not to answer. For example, response was *I would rather not say*, or *Go on to the next question*.
 - b. The question was asked, but the participant does not know, does not remember, or does not understand the statement.

**** If "unknown" is used more than 4 times on the questionnaire it is no longer considered valid for research. Do your best to have the participant give you an answer listed on the response key.****

5. Press on the response on the form in Redcap.
6. When the participant asks about the meaning of any item or tries to qualify a statement, simply repeat the statement. For example:

Participant: *What do you mean by bothered?*

Interviewer: *I was bothered by things that usually don't bother me. Did you feel that way rarely or none of the time, some or a little of the time, occasionally or moderate amount of time, or most or all of the time during the past week?*

7. When the participant still asks about the meaning or says he/she does not understand, check **9** = refused or do not know. Do not try to interpret the statement for the participant.

Training and Certification of Staff

New Staff

- Given Protocol to read, understand, ask questions to Supervisor
- Protocol is demonstrated by Supervisor
- New Staff observes other Techs performing Protocol
- New Staff practices Protocol on staff and volunteers
- New Staff performs Protocol on participant with Supervisor or Certified Tech observing
- When Supervisor feels New Staff is proficient in Protocol, Supervisor will certify New Staff
- Certified New Staff will perform Protocol on own
- Certification date is noted in Certification Log

Recertification of Staff

- Occurs when there is a major deviation on Supervisor Observations or a new study with a new protocol is introduced into the exam
- Protocol is demonstrated by Supervisor
- Staff observes other Techs performing Protocol
- When Supervisor feels Staff is proficient in Protocol, Supervisor will recertify Staff
- Recertification date is noted in Certification Log

Date: _____

Tech ID # _____

Quarter: _____

Supervisor: _____

Participant label: _____

CES-D Supervisor Checklist

Check that each procedure is carried out correctly. Check yes if correct or no if incorrect. Provide an explanation of the incorrect item. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the exam.

Yes	No	CES-D
		SCRIPT: <i>The questions below ask about your feelings. For each of the following statements, please say if you felt that way <u>during the past week</u>.</i>
		Hand the response sheet to the participant and explain the response options. The following definitions should be given: <u>Code</u> Rarely or none of the time (< one full day) Some or a little of the time (1-2 days) Occasionally or moderate amount of time (3-4 days) Most of the time (5-7 days)
		Read each item as it is written on the form, prefacing questions 1, 6 and 11 with the statement <i>During the past week</i> , and then continuing with the response categories.
		Press the response on the form in Redcap
		When the participant asks about the meaning of any item or tries to qualify a statement, simply repeat the statement.
		If the participant is unable to read the response sheets, the interviewer should read each response as well as the question referring to their feelings in the past week.

Yes	No	Technician Review
		Did the technician introduce the set of questions with clear explanation?
		Did the technician ask the questions exactly as written on the form?
		Did the technician correctly clarify any questions the participant had?
		Did the technician score the participant's responses correctly?
		Did the technician review the form for completeness?

Date: _____

Tech ID # _____

Quarter: _____

Supervisor: _____

Participant label: _____

CES-D Supervisor Checklist

Yes	No	Deviations
		Did the tech perform any minor deviations?
		Did the tech perform any major deviations?
Comments/Corrections/Deviations: 		
Supervisor Signature:		
Date:		

Rarely or none of the time (Less than 1 day)

Some or a little of the time (1-2 days)

Occasionally or moderate amount of time (3-4 days)

Most or all of the time (5-7 days)

Administration of Physical Activity Questionnaire
Rest and Activity for a Typical Day (Tech 16)

1. Explain that the first section is Rest and Activity for a Typical Day (24 hours).
2. The day is broken up into different types of activities and a typical day is considered MOST days of the week.
3. Read through each activity and do NOT clarify.
 - **Sleep**
 - Example: napping during the day and actual night sleep.
 - **Sedentary**
 - Example: sitting in the car, eating meals, TV, computer, etc.
 - **Slight Activity**
 - Example: walking to the car, shopping, standing in line, etc.
 - **Moderate Activity**
 - **Heavy Activity**

Explain that a total number of hours for a typical day must equal 24 hours.

4. This should capture over the past year.
5. Make adjustments according to participant until the total number of hours equals 24.

Administration of Physical Activity Questionnaire Time Spent Actually Doing the Activity

Introductory Script:

Now I'll ask you about your Physical Activities. Only include time spent actually doing 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 **Vigorous Activities**. Vigorous activities increase your heart rate, or make you sweat doing them, or make your breathe hard, or raise you body temperature. If you do an activity but not vigorously, please include it later when I ask you about other non-strenuous activities.*

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

1. Read through each **Vigorous Activity** question.
 - a. If answered NO, move to next question.
 - b. If answered YES, move below to answer,
 - i. How many months did you do this activity?
 - ii. How many times per month did you do this activity?
 - iii. How long did you do this activity on average each time? (# of Minute)
 - c. If answered UNKNOWN, Click on Unknown

****NOTE: If jogging is done on a treadmill, record under machine. Also, clarify with the participant that vigorous running is outside for question 1.****

Now, I'd like to ask you about more leisurely activities.

2. Read through each **Leisurely Activity** question and code the same as vigorous.
3. Leisurely Activity is less strenuous then Vigorous.
4. For ALL estimates, round up to the nearest whole number.

Now I'm going to ask you some questions about your physical activity during the past year at WORK ONLY

5. Define “do you work” as currently working as of the past year.
6. This does NOT include stay at home mothers, but DOES include paying jobs and volunteer work. Volunteer work should be prompted for if the participant does not offer the information.
7. If YES code the number of hours worked per week.

At work do you...Sit, Stand, or Walk.

8. Circle: **NEVER, SELDOM, SOMETIMES, OFTEN, or ALWAYS.**

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 or play computer games or play video games?

9. Responses: **none or <1 hour**
 1 hour
 2 hours
 3 hours
 4 hours
 5 or more hours

Training and Certification of Staff

New Staff

- Given Protocol to read, understand, ask questions to Supervisor
- Protocol is demonstrated by Supervisor
- New Staff observes other Techs performing Protocol
- New Staff practices Protocol on staff and volunteers
- New Staff performs Protocol on participant with Supervisor or Certified Tech observing
- When Supervisor feels New Staff is proficient in Protocol, Supervisor will certify New Staff
- Certified New Staff will perform Protocol on own
- Certification date is noted in Certification Log

Recertification of Staff

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Date: _____ Tech ID# _____ Quarter: I, II, III, IV (circle one)
 Supervisor: Emily Manders Participant Label _____

Yes	No	Physical Activity – Part One
		The tech explains that the first section is <u>Rest and Activity for a Typical Day over the past year</u> (24 hours).
		The tech explains that it has to be a whole number and it has to equal 24 hours.
		The tech reads through each activity. <ul style="list-style-type: none"> ▪ Sleep ▪ Sedentary ▪ Slight Activity ▪ Moderate Activity ▪ Heavy Activity
		Examples are given as needed
		Adjustments are made according to the participant until the total number of hours equals 24
		The tech does not coach them or help them fill in the numbers.

Yes	No	Physical Activities – Vigorous (parts 2 and 3)
		<p>SCRIPT: <i>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.</i></p> <p><i>First I'll ask about your vigorous activities. Vigorous activities increase your heart rate, or make you sweat doing them, or make you 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.</i></p> <p><i>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.</i></p>
		Read each item as it is written on the form. Clarify as necessary.
		Click on the response in the RedCap survey
		Physical Activities – non-strenuous (part 4)
		SCRIPT: <i>Now I'd like to ask you about more leisurely activities. In the past 12 months for at least one hour total time in any month did you...</i>

Date: _____ Tech ID# _____ Quarter: I, II, III, IV (circle one)
 Supervisor: Emily Manders Participant Label _____

		Read each item as it is written on the form. Clarify as necessary.
		Click on the response in the RedCap survey
		SCRIPT: <i>Now I'm going to ask you some questions about your physical activity during the past year at <u>WORK ONLY</u></i>
		Read the questions and code responses. Include volunteer work. Do not include stay at home moms.
		SCRIPT: <i>My next question is about your leisure time.</i>
		Read the questions and code responses. <u>Code</u> none or < 1 hour 1 hour 2 hours 3 hours 4 hours 5 or more hours Unknown

Date: _____ Tech ID# _____ Quarter: I, II, III, IV (circle one)
 Supervisor: Emily Manders Participant Label _____

Yes	No	Technician Review
		Did the technician introduce the set of questions with clear explanation?
		Did the technician ask the questions exactly as written on the form?
		Did the technician correctly use the answer key?
		Did the technician correctly clarify any questions the participant had?
		Did the technician score the participant's responses correctly?
		Did the technician review the form for completeness?

Yes	No	Deviations
		Did the tech perform any minor deviations?
		Did the tech perform any major deviations?
Comments/Corrections/Deviations:		
Supervisor Initials:		
Date:		

Rosow-Breslau Questions

A. Rationale & Background

Respondents' self-assessments of health may raise questions about the validity of such judgments. However, we are not interested in the literal details of people's medical condition as much as in the behavioral consequences, their physical capacity for role fulfillment and social participation. We are primarily concerned with the *functional* health which old people report, i.e., the degree to which they claim they can manage adequately or are restricted in their activities because of their physical condition or capacity. *Breslau, M, Rosow, I: A Guttman Health Scale for the Aged. 556-559*

B. Methods

The method of assessing physical functioning is **self-report**. The questions assess the degree of difficulty that a person has performing a specific activity. This form has several important purposes:

1. This data will enable us to assess the level of independence and function in the study population.
2. It is hypothesized that impairments of physical function may be a risk factor for cardiovascular end points and progression of disease.
3. It will measure loss of physical functioning as a consequence of cardiovascular disease.

C. Procedures

Questions:

Coding

No, unable to do
Yes, independent
Does not do
Unknown

1. *Are you able to do heavy work around the house, like shovel snow or wash windows, walls, or floors without help?* (Scrub floors, wash windows, rake leaves, and mow lawn).
2. *Are you able to walk half a mile without help?* (Walk one half mile or 4-6 blocks without stopping for more than 5 minutes).
3. *Are you able to walk up and down one flight of stairs without help?*

Training and Certification of Staff

New Staff

- Given Protocol to read, understand, ask questions to Supervisor
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Recertification of Staff

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Date: _____ Tech ID # _____ Quarter: _____
 Supervisor: _____ Participant label: _____

**Rosow-Breslau Supervisor Checklist –
 Generation 3**

Check that each procedure is carried out correctly. Check yes if correct or no if incorrect. Provide an explanation of the incorrect item. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the exam.

Yes	No	Rosow-Breslau Questions
		Are you able to do heavy work around the house, like shovel snow or wash windows, walls, or floors without help? (Scrub floors, wash windows, rake leaves, mow lawn).
		Are you able to walk half a mile without help? (Walk one half mile or 4-6 blocks without stopping for more than 5 minutes).
		Are you able to walk up and down one flight of stairs without help?

Yes	No	Technician Review
		Did the technician introduce the set of questions with clear explanation?
		Did the technician ask the questions exactly as written on the form?
		Did the technician correctly clarify any questions the participant had?
		Did the technician correctly use the answer key?
		Did the technician score the participant's responses correctly?
		Did the technician review the form for completeness?

Yes	No	Deviations
		Did the tech perform any minor deviations?
		Did the tech perform any major deviations?
Comments/Corrections/Deviations:		
Supervisor Signature:		
Date:		

T08 - Respiratory Disease Q

FHS_IDTYPE_ID _____

Name: [lastname], [firstname] DOB:

[dob]

Age: [age] Last Exam: [lastexamdate]

Sex: [sex] Last Medical Health Update: [lastmhupdate]

Respiratory Disease

Age at last exam _____

Form is intentionally left blank

Reason why form was left blank _____

Technician Number

- 19 -
- 556 -
- 701 -
- 718 -
- 725 -
- 778 -
- 788 -
- 794 -
- 857 -
- 865 -
- 866 -
- 867 -
- 868 -
- 869 -
- 870 -
- 871 -
-

Respiratory Diagnoses

Since your last exam ([lastexamdate]). . .

Have you had asthma?

- No
- Yes
- Unknown

If "Yes"

Do you still have asthma?

- No
- Yes
- Unknown

Was the asthma diagnosed by a doctor or other health care professional?

- No
- Yes
- Unknown

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 EVER had any of the following conditions diagnosed by a doctor or other health care professional? Chronic Bronchitis

- No
 Yes
 Unknown

Emphysema

- No
 Yes
 Unknown

COPD (Chronic Obstructive Pulmonary Disease)

- No
 Yes
 Unknown

Sleep Apnea

- No
 Yes
 Unknown

Pulmonary Fibrosis

- No
 Yes
 Unknown

Additional Comments

Respiratory Disease

Supervisor Observations for Respiratory Questionnaire

Yes	No	
		Respiratory questionnaire is administered. Questions are asked exactly as they are listed on the page.

Yes	No	Technician Review
		Did the technician introduce the set of questions with clear explanation?
		Did the technician ask the questions exactly as written on the form?
		Did the technician correctly clarify any questions the participant had?
		Did the technician correctly use the answer key?
		Did the technician score the participant's responses correctly?
		Did the technician review the form for completeness?

Yes	No	Deviations
		Did the tech perform any minor deviations?
		Did the tech perform any major deviations?

Comments/Corrections/Deviations:

Supervisor Signature:	Date:
------------------------------	--------------

Sociodemographics and Subjective Health

This is a self-reported form. The participant will fill this questionnaire out in clinic. Once the participant is done with the form a clinic staff member will review the form for completeness. If any blanks are left the question will be flagged and the participant will be asked to fill in the blank.

Question 1: What is your current marital status?

- 1=single/never married,
- 2=married/living as married/living with partner
- 3=separated
- 4=divorced
- 5=widowed
- 9=prefer not to answer

Question 2: What is the highest degree or level of school you have completed? (if currently enrolled, mark the highest grade completed, degree received)

- 0= no schooling
- 1=grades 1-8
- 2=grades 9-11
- 3=completed high school (12th grade) or GED
- 4=some college but no degree
- 5=technical school certificate
- 6=associate degree (Junior college AA, AS)
- 7=Bachelor's degree (BA, AB, BS)
- 8=graduate or professional degree (master's, doctorate, MD, etc.)
- 9=prefer not to answer

Question 3: Please choose which of the following best describes your current employment status?

- 0=homemaker, not working outside the home
- 1=employed (or self-employed) full time
- 2=employed (or self-employed) part time
- 3=employed, but on leave for health reasons
- 4=employed, but temporarily away from my job
- 5=unemployed or laid off
- 6=retired from my usual occupation and not working
- 7= retired from my usual occupation but working for pay
- 8= retired from my usual occupation but volunteering
- 9=prefer not to answer
- 10=unemployed due to disability

11= full-time student

Question 4: What is your current occupation? Write in

Question 5: Using the occupation drop down list, choose the code that best describes your occupation.

Question 6: Please select which income group best represents your combined family income for the past 12 months.

1=under \$20,000

2 =\$20,000 – \$34,999

3 =\$35,000 – \$54,999

4 =\$55,000 – \$74,999

5 =\$75,000 – \$100,000

6 =over \$100,000

99=prefer not to answer

Question 7: How many people are supported by this income?

Question 8: Do you have some form of health insurance? 0=No, 1=Yes

If the participant answers yes, make sure that the participant circles what type of insurance they have from the insurance plan list.

Question 9: Do you have prescription drug coverage

OCCUPATION CODING

- 01= Homemaker
- 02= Retired
- 03= Self Employed Business Owner
- 04= M.D. / Dentist
- 05= Lawyer/ Judge
- 06= Psychologist / Social Worker / Mental Health Counselor
- 07= Scientist / Research
- 08= Engineer / Computer Science
- 09= Banker / Accountant
- 10= Manager / Consultant (e.g. Production Manager)
- 11= Administer (e.g. Personnel)
- 12= Educator
- 13= Nurse / Medical Personnel
- 14= Laboratory Technician
- 15= Physical / Occupational / Speech Therapist
- 16= Secretary/ Clerk / Data Entry
- 17= Retail / Cashier
- 18= Sales / Marketing / Insurance
- 19= Realtor
- 20= Writer / Editor
- 21= Artist / Graphic Designer / Craftsperson
- 22= Musician
- 23= Police / Fire / Security / Military
- 24= Factory / Assembly
- 25= Mechanic
- 26= Restaurant / Food Worker
- 27= Skilled Labor (e.g. Plumber, Carpenter, Painter, Hairdresser)
- 28= General Labor (e.g. Custodian, Delivery, Mailman, Truck Driver)
- 29= Heavy Labor (e.g. Construction, Landscaping)
- 30= Clergy (minister, Priest, Rabbi)
- 31= Sports Pro / Coach / Exercise Instructor
- 32= Statistician
- 33= Student
- 88= Other

SF-12 Health Survey

The Quality of Life form has twelve questions and is designed to collect information about the participant's perceived physical and emotional health, as they relate to quality of daily living.

Q1 asks the participant to rank his/her general health on a five-point response scale: *Excellent, Very Good, Good, Fair, Poor*.

Q2 and Q3 address the extent to which a participant's health limits his/her activities regarding moderate activities and climbing stairs, using a three-point response scale: *No-not limited, Yes- limited a little, Yes- limited a lot*.

Q4-Q7 ask the participant to assess whether physical and emotional problems have impacted his/her ability to perform work tasks or regular daily activities during the previous four weeks. A *Yes* or *No* response is required.

Q8 asks the participant how much pain interfered with his/her normal work during the previous four weeks, using a five-point response scale: *Not at all, A little bit, Moderately, Quite a bit, Extremely*.

Q9-Q12 ask the participant how he/she has felt during the previous four weeks, using a six point response scale: *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*.

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Q9-Q12 ask the participant how he/she has felt during the previous four weeks, using a six point response scale: *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*.

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Observed Physical Performance

A. Overview:

An objective performance measure of physical functioning is an assessment instrument in which an individual is asked to perform a specific task and is evaluated in an objective, standardized manner using predetermined criteria, which may include counting of repetitions or timing of the activity as appropriate. Two theoretical models of the pathway from disease to disability have been developed. The first comes from the World Health Organization and goes from disease to impairment to disability, to handicapped. The second, which is being used more now by geriatricians and aging researchers, progresses from disease, to impairment, to functional limitations, to disability.

Definitions

Impairment: Dysfunctional and structural abnormalities in specific body systems, such as the musculoskeletal system or the cardiovascular system.

Functional limitations: Restrictions in basic physical and mental actions, including things such as ambulation reaching, and grasping.

Disability: Difficulty doing activities of daily life, including not only personal care, but household management, jobs, and hobbies.

B. Methods:

During all tests, participant safety is paramount. Participants who do not feel safe or who are unable to perform a test should not be pressed. All procedures should be clearly demonstrated to the participant prior to performing any test and the participant should be queried to ensure that they understand the instructions. If it is obvious that the participant has not understood the directions, reread the standard instructions. You will be demonstrating each maneuver. Someone who may not completely understand the verbal instructions may still be able to perform the test following the demonstration.

D. A note on encouragement:

If a participant expresses doubt as to whether he or she can perform the task, ask the participant whether they would like to try. If they say yes, proceed with the task but if they say no, honor the participant's choice to decline the testing.

Information on Observed Physical Performance found in this section was obtained through:

Guralnik MD, PhD, Jack. Assessing Physical Performance in the Older Patient: An overview of the Short Physical Performance Battery (SPPB). CD-ROM. 2003

JAMAR Hand Grip Strength Test:

Introductory script: *This instrument will measure your grip strength. I will first explain what I would like you to do, then I will demonstrate it for you, and then I will ask you to try it for me.*

The instrument is a little heavy, so be careful. When I tell you, I want you to squeeze the instrument as hard as you can. Do not expect the handle to move very much.

1. Participant is seated in chair with arms, forearm resting on chair arm, elbow at about a 90 degree angle.
2. Participant should hold JAMAR in upright position, wrist in neutral position, JAMAR facing the technician.
3. Make sure that red peak-hold needle is set to zero.
4. Tell participant to squeeze as hard as s/he can, and squeeze until you tell s/he to stop. Hold squeeze for a 3 to 5-1000 second count.
5. Take back JAMAR, hold at eye level at about a foot from your eyes and record reading on the kilogram scale. If directly in the middle of the scale then the reading is the odd number between the two even hash marks; otherwise record as the closest hash mark.
7. Repeat steps until three measurements are recorded with the right hand.
8. Repeat steps for three trials with the left hand.
9. **If only one hand is completed then test is still coded as completed.**

Equipment and Calibration for Hand Grip

Equipment:

- JAMAR Dynamometer
- Table
- Chair

Calibration:

Hand Grip	Daily		Yearly	
Zero Reading	X			
Professional Calibration			X	

Training and Certification of Staff

New Staff

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Date: _____ Tech ID # _____ Quarter: _____
 Supervisor: _____ Participant label: _____

Observed Physical Performance Supervisor Checklist

Check that each procedure is carried out correctly. Check yes if correct or no if incorrect. Provide an explanation of the incorrect item. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the exam.

Yes	No	JAMAR Hand Grip Strength Test
		Introductory script: <i>This instrument will measure your grip strength. The instrument is a little heavy, so be careful. When I tell you, I want you to squeeze the instrument as hard as you can. Do not expect the handle to move very much.</i>
		Participant is seated in chair with arms, forearm resting on chair arm, elbow at about a 90 degree angle.
		Participant should hold JAMAR in upright position, wrist in neutral position, JAMAR facing the technician.
		Make sure that red peak-hold needle is set to zero.
		Tell participant to squeeze as hard as s/he can, and squeeze until you tell s/he to stop. Hold squeeze for a 3 to 5-1000 second count.
		Take back JAMAR, hold at eye level at about a foot from your eyes and record reading on the kilogram scale. If directly in the middle of the scale then the reading is the odd number between the two even hash marks; otherwise record as the closest hash mark.
		Repeat steps until three measurements are recorded with the right hand.
		Repeat steps for three trials with the left hand.

Yes	No	Deviations
		Did the tech perform any minor deviations?
		Did the tech perform any major deviations?
Comments/Corrections/Deviations:		
Supervisor Signature:		
Date:		

ECG Set Up and Lead Placement

1. Ask the participant to lie supine on the examination table.
2. Inform them you will be performing an ECG and read the following script:

An ECG is made up of waves showing the electrical activity in different parts of the heart. In order to get an accurate test please try to lie still. The test takes approximately 10 minutes.
3. Tell the participant you will be placing electrodes on their arms, legs, and chest. Inform them you will be cleaning those areas with Tens Cote Cleaner as well as making marks on their chest with a cosmetic pencil.
4. If he/she is known to be allergic to alcohol, prepare the areas of electrode placement by rubbing with water and drying with a washcloth. If allergies are denied, prepare areas V1, V2-V6, RA, RL, LA, LL, by wiping with a Tens Cote Cleaner. Let dry.
5. **V1:** The first intercostal space is palpated just below the clavicle. Count down and identify the 4th intercostal space just below the fourth rib. **Point V1** is just to the right of the sternum in the *fourth* intercostal space. Make a small line with a marking pencil here to show where the ECG lead should be placed.
6. **V2:** Should be at the same level as **Point V1** and immediately to the left of the sternum. Make a small line with a marking pencil to show where the ECG lead should be placed.
7. To locate the horizontal reference level for electrodes (**Point E**), starting from **V2**, locate the **fifth** intercostal space. Move your finger in the **5th** intercostal space laterally to where the midclavicular (center of the chest where you feel a bend in the clavicle) line intersects the **fifth** intercostal space. Make a horizontal line at this point.

Mark the exact transverse (horizontal) level at this spot with the midsternal line. It should be about one inch (1”) below **V1** and **V2** placements.
8. **V6:** Move the participant’s elbow laterally away from the body. Mark the midaxillary line in the exact vertical center plane of the thorax down to the intersection of the horizontal plane marked by the location of **E**. This is the exact location of **V6**. (**NOTE:** It is a common mistake to locate the midaxillary line too far anteriorly, toward the **V5** location).

9. **V4:** Place the # arm of the Heart Square firmly across the lower sternum at the level of **Point E** (as you face the participant, the writing on the Heart Square will appear upside down and backwards). Adjust the **E** and **V6** arms of the Heart Square so they are both perpendicular to the long axis of the thoracic spine at the level of the **E** position. The **E** arm should be exactly horizontal. If the participant is lying flat, the **V6** arm should be exactly vertical.

Slide the **V6** arm so the **0** point (the *arrow* labeled **V6**) is at the marked location for **V6**. Double check that the **E** arm is still in the correct spot.

V4: On the **V6** arm (the slide), find the number corresponding to the **E** measurement. Following the corresponding 45 degree line to the surface (e.g. 16) and mark the location following the inside of the square. Place electrodes on **TOP** of the breast.

The participant may now lower the left arm in a more comfortable position.

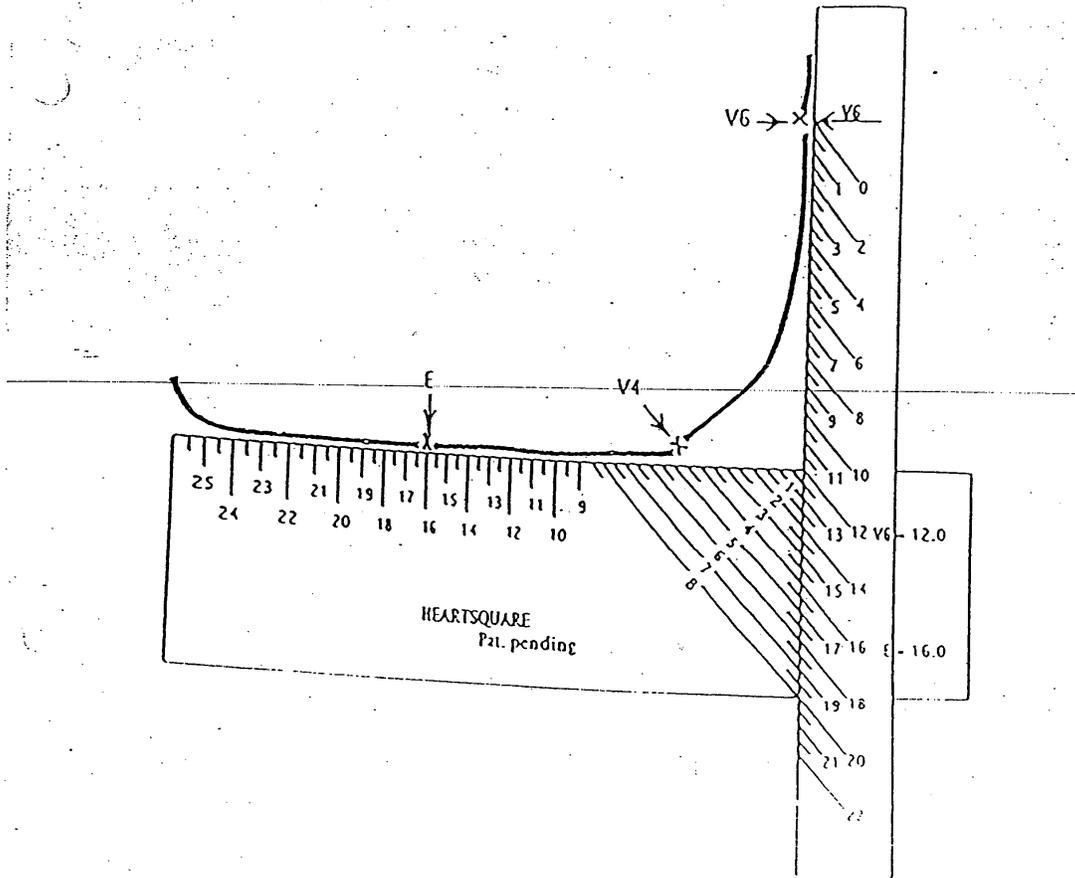
10. **V3:** Exactly halfway between **V2** and **V4**.
11. **V5:** Exactly halfway between **V4** and **V6**.
12. If he/she is known to be allergic to alcohol wipes, prepare the areas of electrode placement by rubbing with water and drying with a washcloth. If allergies are denied, prepare the areas by wiping with an alcohol wipe and drying with a washcloth.

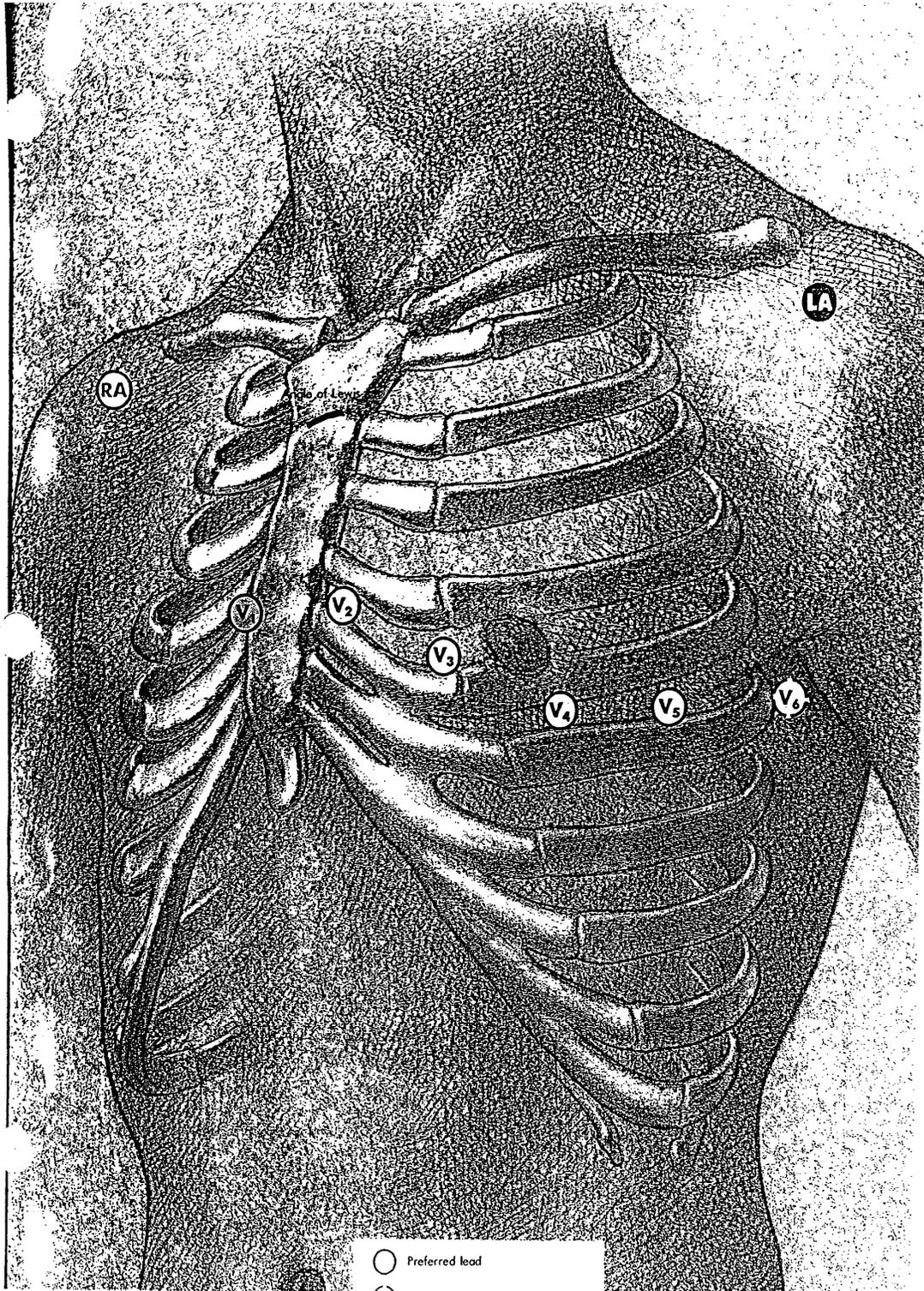
NOTE: Place the electrodes on the participant and hook up the leads before entering the data in the ECG machine. This will allow ample time for the participant to relax and the machine interference to smooth out.

13. Attach limb leads in the following order: right arm (RA), right leg (RL), left arm (LA), left leg (LL) parallel to the limb with tabs facing toward the heart. This will avoid lead reversal.
14. The body of the electrode is placed centrally at the pencil mark with the tab extending downward. Precordial electrodes are attached in the following order: V1, V2, V3, V4, V5, V6. Recheck all leads for proper placement.
15. Ask the participant to lie still and relax. In the computer, enter the participants Name, ID, Age, Height, Weight, and Gender. Enter the Exam Cycle, Location (1=clinic), and your Tech ID.
16. The ECG is printed and reviewed for errors. If ECG needs to be run at **5 mmHg** because of high voltage (if the standard **10 mmHg** is beyond the lines of the ECG

paper), highlight (yellow or orange highlighter) the **5 mmHg** on the bottom of the printed ECG. On the top margin of the tracing write “*1/2 STANDARD*” using a bold magic marker.

17. Leads are checked again for proper placement and disconnected. Electrodes are carefully removed.
18. After each use, wash the Heart Square gently with soap and water (1 part detergent to at least 20 parts water, approximately 3 drops of detergent to one cup of water) and gently wipe dry with a soft cloth.





Equipment for ECG

- ECG Machines: GE MAC5500 (3)

Marquette Electronics

100 Marquette Drive

Jupiter, FL 33468-9100

Sales Rep: Kevin Manning

781-439-5969 (cell)

Kevin.manning@ge.com

- ECG Carts
- MUSE

Training and Certification of Staff

New Staff

- Given Protocol to read, understand, ask questions to Supervisor
- Protocol is demonstrated by Supervisor
- New Staff observes other Techs performing Protocol
- New Staff practices Protocol on staff and volunteers
- New Staff performs Protocol on participant with Supervisor or Certified Tech observing
- When Supervisor feels New Staff is proficient in Protocol, Supervisor will certify New Staff
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Date: _____

Tech ID# _____

Supervisor: _____

Participant _____

ECG Supervisor Checklist

Check that each procedure is carried out correctly. Check yes if correct or no if incorrect. Provide an explanation of the incorrect item. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the exam.

Yes	No	ECG Procedures
		Participant is informed that ECG is going to be done. Procedure is explained. Participant is asked to lie on bed, get comfortable.
		Tech establishes a rapport with participant so participant is at ease with procedure. Answers any questions participant may have.
		Electrode location V2 is located in the 4 th intercostals space at the left sternal border, a mark is made with pencil.
		V1 is found at the same level as V2 but at the right sternal border, a mark is made.
		The E point is located at the intersection of the 5 th intercostal space and the mid-clavicular line, a mark is made.
		A line is drawn at mid axillary in exact vertical center plane of the thorax.
		V6 is located in the mid axilla at the same level as the E point. (The heart square should be firmly placed on the body and kept on a horizontal plane from the E point to the mid-axillary point).
		The difference between the E measurement and V6 measurement is calculated.
		The difference from the above calculation is located in the heart square and V4 is located on the chest, a mark is made.
		V3 is located midway between V2 and V4, a mark is made.
		V5 is located midway between V4 and V6, a mark is made
		Tens Cote wipe is used to clean each area, RA, RL, LA, LL, V1 – V6
		RA electrode is located on the upper (dorsal) surface of right forearm, placed with tab extending away from body.
		RL electrode is located on the inside surface of the right lower leg, placed with tab extending away from body.
		LA electrode is located on the upper (dorsal) surface of left forearm, placed with tab extending away from body.
		LL electrode is located on the inside surface left lower leg, placed with tab extending away from body.
		Chest Electrodes are placed at V1, V2, V3, V4, V5, V6 with the body of the electrode placed centrally on each pencil

		measurement, tab extending down.
Yes	No	ECG Procedures (cont'd)
		Leads are connected to electrodes in the following order: RA, RL, LA, LL, V1 – V6
		All leads are rechecked for proper placement
		The participant's identifying information is typed into the MAC.
		Participant is requested to relax and lie quietly while ECG recording is in process.
		When tracing appears acceptable, the ECG is printed and reviewed for errors
		All leads are rechecked for proper placement and then disconnected and electrodes gently removed
		2 copies of the ECG is printed and stamped with the correct exam number.

Comments/Corrections:
Supervisor:
Date:

Seated Blood Pressure

A. Equipment:

1. One standard Litman stethoscope tubing and earpieces with bell: Classic II 3M
2. One standard mercury column sphygmomanometer: Baumanometer (clinic)
3. Aneroid sphygmomanometer (offsite)
4. BP cuffs in four sizes (all Latex free)

Thigh adult cuff
Large adult cuff
Regular adult cuff
Pediatric cuff

B. Blood Pressure Cuff Placement:

1. Bare participant's left arm to above the point of the shoulder.
2. Determine correct cuff size using guidelines inside the cuff.
3. Palpate the brachial artery.
4. With participant seated, place the appropriate cuff around the upper left arm. The midpoint of the length of the bladder should lie over the brachial artery. Each cuff has an artery marker. The mid-height of the cuff should be at heart level.
5. Place the lower edge of the cuff, with its tubing connections, about one inch (1") above the natural crease across the inner aspect of the elbow.
6. Wrap the cuff snugly about the arm, with the palm of the participant's hand turned upward.
7. If the subject has had a left-sided mastectomy, the right arm may be used for blood pressure measurement. If right arm is used, note it on the form.

C. Determination of Maximal Inflation Level

For each participant, determine the maximal inflation level, or the pressure to which the cuff is to be inflated for blood pressure measurement. This assures that the cuff pressure at the start of the reading exceeds the systolic blood pressure and thus allows the first Kortokoff sound to be heard.

1. Attach the cuff tubing to the sphygmomanometer.
2. Palpate the radial pulse.
3. Inflate the cuff rapidly until the radial pulse is no longer felt (palpated systolic pressure) by inflating rapidly to 70 mmHg, then inflating by 10mmHg increments.
4. Deflate the cuff quickly and completely.
5. The maximal inflation level is 30 mmHg **above** the palpated systolic pressure.

D. Guidelines for Accurate Blood Pressure Readings:

1. The participant should be in a seated position for at least 5 minutes before the blood pressure is measured with both feet remaining flat on the floor.
2. All readings are made to the nearest even digit.
3. Any reading which appears to fall exactly between marking on the mercury column should be read to the next higher marking (i.e. 2, 4, 6, 8, or 0).
4. All readings are made to the top of the meniscus, the rounded surface of the mercury column.
5. When the pressure is released quickly from a high level, a vacuum is formed above the mercury and the meniscus is distorted. Allow a few moments for it to reappear before reading the manometer.

E. Blood Pressure Readings:

1. Following any previous inflation, wait at least 30 seconds after the cuff has completely deflated.
2. By closing the thumb valve and squeezing the bulb, inflate the cuff at a rapid but smooth continuous rate to the maximal inflation level (30 mmHg above palpated systolic pressure).

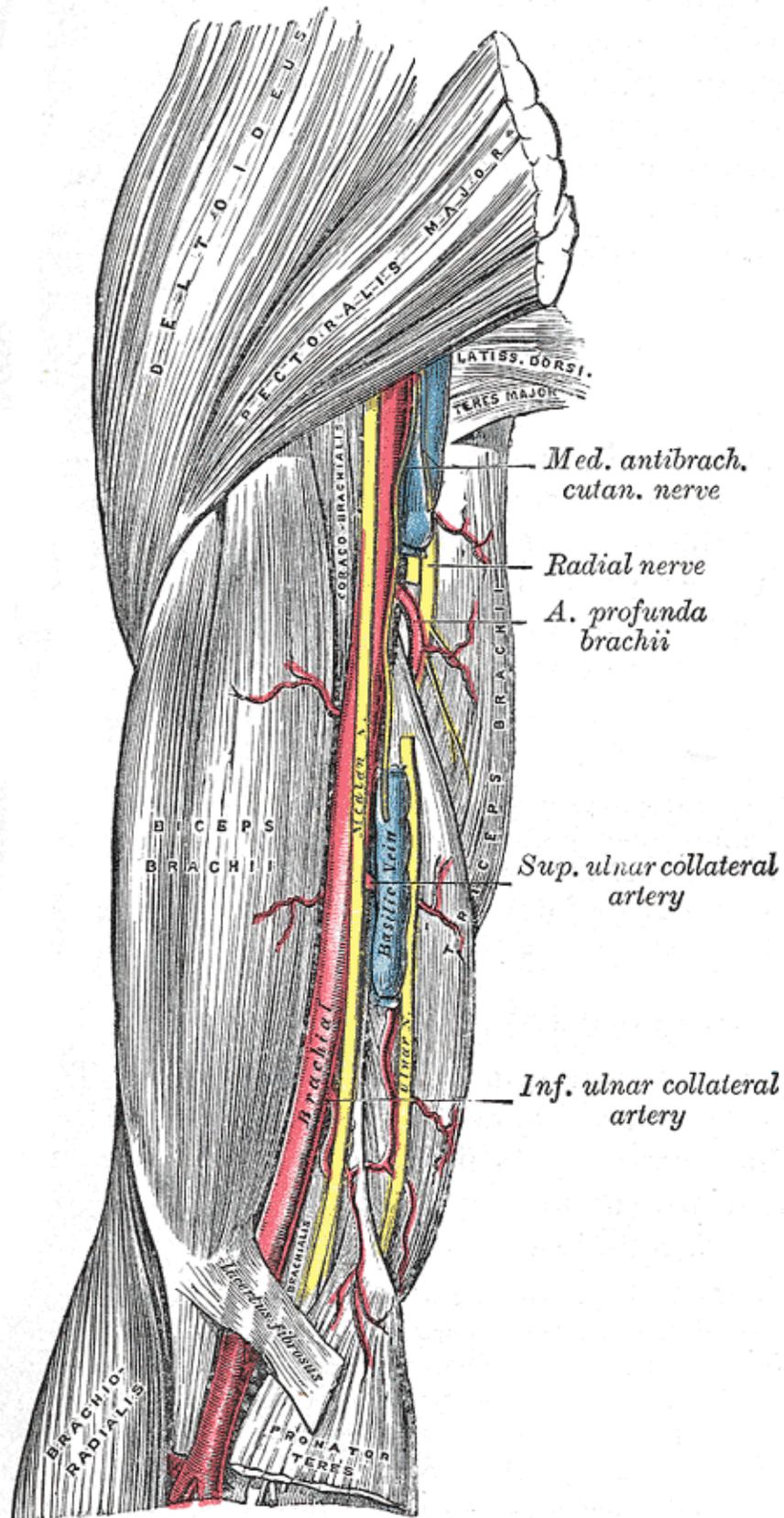
3. The examiner's eyes should be level with the mid-range of the manometer scale and focused at the level to which the pressure will be raised.
4. Open the thumb valve slightly. Allow the cuff to deflate, maintaining a constant rate of deflation at approximately 2 mmHg per second.
5. Using the bell of the stethoscope, listen throughout the entire range of deflation, from the maximum pressure past the systolic reading (the pressure where the FIRST regular sound is heard), until 10 mmHg BELOW the level of the diastolic reading (that is, 10 mmHg below the level at which the LAST regular sound is heard).
6. Deflate the cuff fully by opening the thumb valve.
7. Remove the stethoscope. Neatly enter systolic and diastolic readings in the spaces provided on the form.

Blood Pressure Equipment

1. Portable standard mercury column sphygmomanometer:
Baumanometer, 300 model; Catalogue #0661-0320
W.A. Baum Co., Inc.
620 Oak Street
Copaigue, NY 11726-3292
(631) 226-3940
Fax (631) 226-3969
<http://www.wabaum.com>
Tech: Larry DiPippo
603-401-1483

2. Bauman latex free blood pressure cuffs in four sizes: regular adult, large adult, pediatric, thigh. (Ordered through AllHealth)

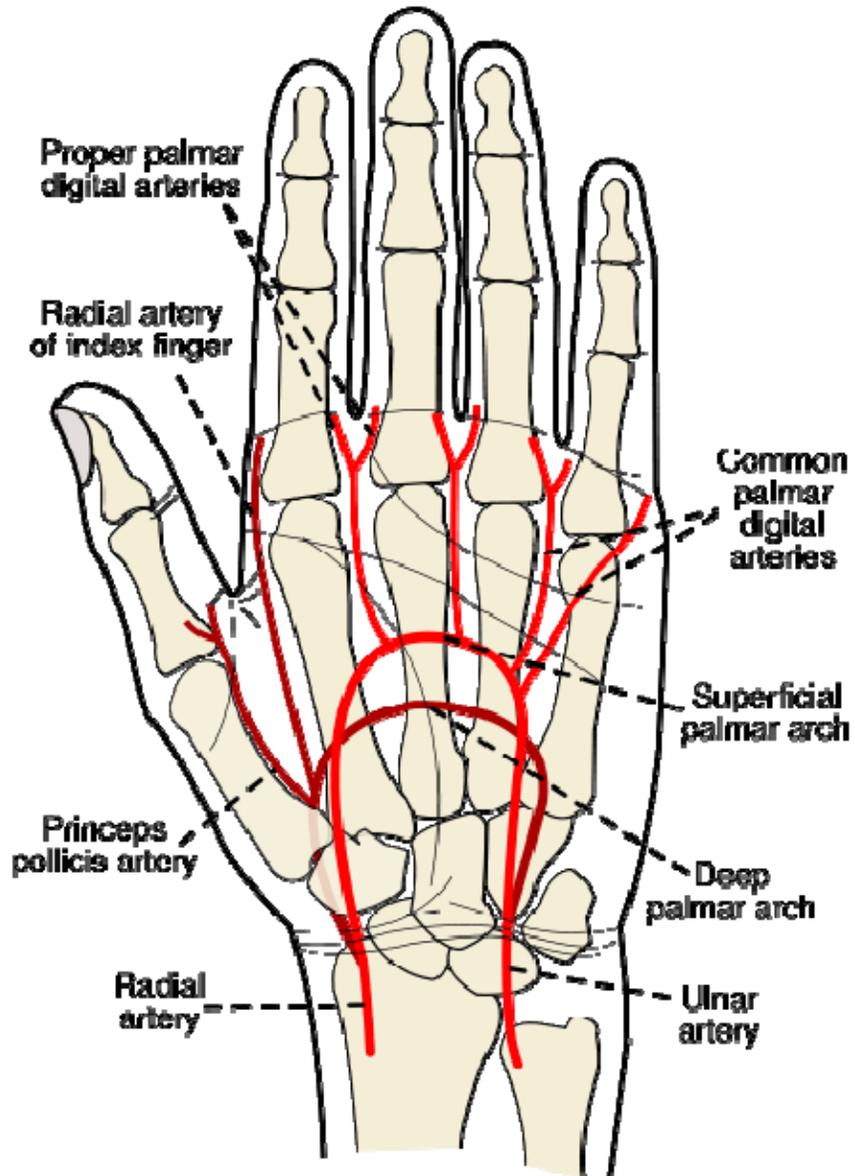
3. Litman stethoscope tubing and earpieces with bell: Classic II



Brachial Artery:

Located between the biceps and triceps, on the medial side of the elbow.

Radial Artery: Located on the thumb side of the wrist.



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THE FRAMINGHAM STUDY

CRITERIA FOR EVENTS

1. Cardiovascular Disease

Cardiovascular disease is considered to have developed if there was a definite manifestation of coronary heart disease, intermittent claudication, congestive heart failure, or stroke or transient ischemic attack in the absence of a previous manifestation of any of these diseases. Criteria for all these events are given below. A person having more than one cardiovascular manifestation within the follow-up period is counted as an incident case only at the time of the first event.

2. Coronary Heart Disease

Subjects are diagnosed as having developed coronary heart disease (CHD) if upon review of the case a panel of three investigators (the Framingham Endpoint Review Committee) agrees on one of the following definite manifestations of CHD: myocardial infarction, coronary insufficiency, angina pectoris, sudden death from CHD, non-sudden death from CHD. Persons with pre-existing CHD at Exam 1 are excluded from the population at risk of developing CHD but may be eligible for studies of prevalent CHD. Pre-existing CHD at Exam 1 is identified by any one of the following diagnoses at Exam 1: definite angina pectoris, definite history of myocardial infarction, definite myocardial infarction by electrocardiogram, doubtful myocardial infarction by electrocardiogram, definite coronary insufficiency by electrocardiogram and history.

The various manifestations of CHD are these:

Angina Pectoris

Brief recurrent chest discomfort of up to 15 minutes duration, precipitated by exertion or emotion and relieved by rest or by nitroglycerine is regarded as angina pectoris (AP) if two physicians interviewing the subject at a Framingham clinic visit or the Framingham Endpoint Review Committee, upon review of medical records, agree that this condition was definitely present. This diagnosis is based solely on evaluation of subjective manifestations. Abnormality of the resting or exercise electrocardiogram is not required for this diagnosis.

Myocardial Infarction

Recent or acute myocardial infarction (MI) is designated when there were at least two of three findings:

- 1) symptoms indicative of ischemia;
- 2) changes in biomarkers of myocardial necrosis;

- 3) serial changes in the electrocardiograms indicating the evolution of an infarction, including the loss of initial QRS potentials (that is, development of “pathologic” Q-waves of 0.04 second duration or greater).

An old or remote myocardial infarction is considered to be present when the electrocardiogram shows a stable pattern including a pathologic Q-wave of 0.04 second or greater or loss of initial QRS potential R-wave in those leads in which this would not be expected to occur. Also, an interim unrecognized MI is indicated when changes from a previous tracing show development of loss of R-wave potential or appearance of pathologic Q-waves not otherwise explained, in persons in whom neither the patient nor his physician considered the possibility of MI. If the patient was asymptomatic for chest pain or upper abdominal pain during the interval at which the unrecognized MI occurred, the event is classified as silent, unrecognized. More weight is given to this finding if a T-wave abnormality is also associated with Q-wave abnormality.

An autopsy report showing an acute, new, or recent infarction of the myocardium is accepted as evidence of an incident myocardial infarction. Because it is not possible to date an old infarction found on autopsy, such evidence is not used in the clinical diagnosis of a new event, unless there was an interim clinical event suspected of being an infarction.

Coronary Insufficiency

The coronary insufficiency syndrome is designated when a history of prolonged ischemic chest pain (> 15 minutes duration) was accompanied by transient ischemic S-T segment and T-wave abnormality in the electrocardiographic tracing but not accompanied by development of Q-wave abnormality or by serum enzyme changes characteristic of myocardial necrosis.

Coronary Heart Disease Death

Death from coronary heart disease is diagnosed as either sudden or nonsudden. For a detailed description of these diagnoses, see 6 below.

3. Stroke

The diagnosis of cerebrovascular disease is based on the occurrence of a clinically evident stroke documented by clinical records reviewed by at least two neurologists. Stroke is defined as the sudden or rapid onset of a focal neurologic deficit persisting for greater than 24 hours. Stroke is further categorized into infarction or hemorrhage.

Hemorrhagic Stroke

The diagnosis of subarachnoid hemorrhage is based on a history suggestive of this process such as abrupt onset headache, with or without change in the level of consciousness, and signs of meningeal irritation with or without other localizing

neurological deficits. Intracerebral hemorrhage is diagnosed clinically by the occurrence of abrupt focal neurologic deficit, often with altered level of consciousness and symptoms of increased intracranial pressure. Hemorrhages are confirmed by imaging.

Ischemic Stroke

A diagnosis of cerebral embolism is made when an established source for embolus including atrial fibrillation, rheumatic heart disease with mitral stenosis, recent myocardial infarction, bacterial endocarditis or other known source is determined. A clinical course consistent with embolic infarction or evidence of other systemic embolism may be present. Symptoms are usually rapid with maximal severity at onset.

Arterothrombotic brain infarction is defined as the sudden onset of a focal neurologic deficit lasting longer than 24 hours, in the absence of:

- 1) known source of embolism (atrial fibrillation, rheumatic heart disease with mitral stenosis, myocardial infarction within preceding six months, bacterial endocarditis);
- 2) intracranial hemorrhage (intracerebral or subarachnoid);
- 3) known hypercoagulable states;
- 4) other disease processes causing focal neurologic deficits (brain tumor, subdural hematoma, hypoglycemia).

Confirmatory imaging supports the diagnosis.

Silent stroke may be documented at the stroke review sessions when a stroke event is determined and an incidental infarct is seen on brain imaging in the absence of a reported clinical event.

Transient ischemic attack

A transient ischemic attack is defined as a focal neurologic deficit of sudden or rapid onset that fully resolves in less than 24 hours.

Stroke Death

Death attributed to stroke is designated when a documented focal neurologic deficit of greater than 24 hours duration preceded death and was responsible for the fatality.

4. Intermittent claudication

Minimum criteria for the subjective diagnosis of intermittent claudication consists of a cramping discomfort in the calf clearly provoked by walking some distance with the pain appearing sooner when walking quickly or uphill and being relieved within a few minutes by rest. This diagnosis is designated if two physicians at a

Framingham clinic visit or the Framingham Endpoint Review Committee, upon review of medical records, agree that this condition is definitely present. A diagnosis of intermittent claudication is based solely on evaluation of subjective manifestations.

5. Congestive heart failure

A definite diagnosis of congestive heart failure requires that a minimum of two major or one major and two minor criteria be present concurrently. The presence of other conditions capable of producing the symptoms and signs are considered in evaluating the findings.

Major Criteria:

- 1) Paroxysmal nocturnal dyspnea or orthopnea;
- 2) Distended neck veins (in other than the supine position);
- 3) Rales;
- 4) Increasing heart size by x-ray;
- 5) Acute pulmonary edema on chest x-ray;
- 6) Ventricular S(3) gallop;
- 7) Increased venous pressure > 16 cm H₂O;
- 8) Hepatojugular reflux;
- 9) Pulmonary edema, visceral congestion, cardiomegaly shown on autopsy;
- 10) Weight loss on CHF Rx: 10 lbs./5days.

Minor criteria:

- 1) Bilateral ankle edema;
- 2) Night cough;
- 3) Dyspnea on ordinary exertion;
- 4) Hepatomegaly;
- 5) Pleural effusion by x-ray;
- 6) Decrease in vital capacity by one-third from maximum record;
- 7) Tachycardia (120 beats per minute or more);
- 8) Pulmonary vascular engorgement on chest x-ray.

6. Coronary heart disease death

Death from coronary heart disease is diagnosed as either sudden or nonsudden.

Nonsudden death from CHD

If the terminal episode lasted longer than one hour, if the available information implies that the cause of death was probably CHD, and if no other cause can be ascribed, this is called nonsudden death from CHD. In making this diagnosis, the

review panel uses prior clinical information as well as information concerning the final illness.

Sudden death from coronary heart disease

If a subject, apparently well, was observed to have died within a few minutes (operationally documented as under one hour) from onset of symptoms and if the cause of death cannot reasonably be attributed on the basis of the full clinical information and the information concerning death to some potentially lethal disease other than coronary heart disease, this is called sudden death and is attributed to coronary heart disease.

7. Cardiovascular disease death

This cause of death is designated when any disease of the heart or blood vessels is considered responsible.

8. All-cause mortality

The fact of death is supported by a death certificate. Additional information is obtained from records supplied by hospital, attending physician, pathologist, medical examiner, or family. The Framingham Endpoint Review Committee reviews all evidence to arrive at the cause of death.

ECG coding for Gen 3/Omni 2/New Offspring Spouse Exam 3

General Comments

The computerized ECGs include measurement of rate, intervals and axis and will be directly transmitted to the MUSE.

Be sure to always look at the last ECG for changes.

Please code the **predominant Rhythm**.

AV BLOCK

1st degree when PR duration is .20 seconds or greater (measured in lead II).

2nd degree when some P waves are not conducted. This comes in two forms a) Mobitz I. When progressive PR prolongation precedes the dropped P wave and b) Mobitz II when QRS complexes are dropped without prior PR prolongation. AV dissociation occurs when P waves and QRS complexes march out independent of each other.

Ventricular Conduction Abnormalities

IV Block

This refers to right and left bundle branch block. Note that the code 1 is used for incomplete BBB and 2 is for complete BBB. For complete BBB the QRS interval should be .120 sec or greater. When the QRS is prolonged, but the pattern is not that of right or left BBB, the indeterminate IV block is coded as follows: 1=QRS .120 sec or greater, 2=QRS of .110 or .100 sec. Remember that the measurements of QRS duration are those made by the examining physician and not by the computer. An RSR' pattern in the absence of QRS prolongation should be coded as normal. When an RSR' pattern occurs with a QRS duration of .090 sec or greater it represents incomplete RBBB.

Hemiblock

1=left anterior. This is present when the QRS axis is -30 or less and small q wave is present in lead I.

2=left posterior. QRS axis is >90 and small q is present in AVF, in absence of evidence of right ventricular hypertrophy.

WPW

A short PR interval is present (typically .12 seconds or less) and a slurred upstroke of the QRS is present (so called delta wave). When these features are both fulfilled, WPW is present. When the PR is .12 or less and a delta wave is possibly present, or when a delta wave is present but the PR is marginally short .13 to .14 seconds, WPW is "maybe" present.

ARRHYTHMIAS

The presence of rhythm disturbances should be made on the basis of examination of the ½ speed rhythm strip which accompanies each ECG. This represents a simultaneous 3 lead recording of the entire 12-lead ECG.

MYOCARDIAL INFARCTION

This is determined on the basis of the appearance of wide (.04 seconds) or deep (1/4 the height of the R wave) q waves. All tracings should be compared to the prior exam ECG which is always provided. The appearance of new, but small q waves should also be regarded as suggestive of MI. Loss of R waves in leads where they were previously present (see prior exam's ECG) should also raise suspicion of MI. A posterior MI is present when $R > S$ in V1, R is .04 seconds in duration, and an upright T wave is recorded in that lead. When criteria are largely, but incompletely fulfilled be sure to code this item as maybe!

ATRIAL ENLARGEMENT

Left Atrial Enlargement: Morris P wave: The terminal portion of the P wave in lead V1 is inverted and measures at least 1mm by 1mm (at normal standardization).

Right Atrial Enlargement: The P wave in inferior leads is peaked with a height of 2.5 mm.

RIGHT VENTRICULAR HYPERTROPHY Definite RVH is present when increased R wave voltage is present in V1 and increase S wave voltage is present in V5 in the absence of RBBB. The sum of RV1 + SV5 should be at least 10.5mm.

LEFT VENTRICULAR HYPERTROPHY

LVH with strain is present when increased voltage is present together with a strain pattern, i.e. downsloping ST.

LVH with mild S-T abnormality is present when voltage criteria are fulfilled but only mild ST-T abnormalities (flattening) are noted.

LVH by voltage only is present when voltage criteria are met without ST abnormality. When complete BBB is present or the tracing is fully paced, LVH should be coded as unknown.

Voltage criteria for LVH:

R > 20mm in any limb lead

R > 11mm in AVL

R in lead I plus S in lead III \geq 25mm

R in V5 or V6; S in V1 or V2:

R \geq 25mm

S \geq 25mm

R or S \geq 30mm

R + S \geq 35mm



Framingham Heart Study

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

RESEARCH EXAMINATION REPORT GEN3/Omni Group 2 EXAM 3

Letter Date _____

Dr. Smith
Sample Avenue
Anytown, USA 95124

Name: Paul Participant
Research Exam Date: 1/1/2000
DOB: xx/xx/xx
ID: x-xxxx

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.

BLOOD PRESSURE:	FIRST READING	SECOND READING
Systolic Blood Pressure	xxx	xxx
Diastolic Blood Pressure	xxx	xxx

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.



Framingham Heart Study

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

If you have any questions, please do not hesitate to contact me.

Examiner _____

Daniel Levy, MD

Director, Framingham Heart Study

OMB No = 0925-0216 4/30/2001

**Framingham Heart Study
Gen3/Omni G2/NOS Exam 3
Laboratory Protocol**

Blood samples are collected from participants in a supine position, after a 12-hour fast.

The following tubes are drawn:

- 4 x 10 mL EDTA blood collection tubes
- 2 x 10 mL Serum blood collection tubes
- 1 x 8 mL CPT [Cell Preparation Tube]
- 1 x 4 mL CPT [Cell Preparation Tube]
- 4 x 4.5 mL Citrate blood collection tubes
- 1 x 3 mL Hirudin blood collection tube

Total volume of fasting blood draw is 93 mL (6.3 T/3.1 ounces).

A second blood sample is collected from participants at peak exercise, in a sitting position.

The following tubes are drawn:

- 1 x 10 mL EDTA blood collection tubes
- 1 x 10 mL Serum blood collection tubes

Total volume of peak exercise blood drawn is 20 mL (1.4 T/0.7 ounces).

Total volume of blood draw at exam is 113 mL (7.7 T/3.8 ounces)

****A small number of participants (N<50), need a cell line blood draw.
If a participant needs a cell line, an additional 8 ml CPT tube is drawn.**

Total volume of blood drawn is 121 ml (8.2/4.1 ounces).

EDTA

1. EDTA whole blood is used for HbA1c, which is measured daily in the FHS laboratory.
2. EDTA plasma is used for Cholesterol, HDL cholesterol, Triglycerides and Glucose which are measured daily in the FHS laboratory.
3. EDTA plasma and red cells are saved in several aliquots for future measurements; stored at -80 C.
4. Buffy coat specimens are collected from the EDTA blood collection tubes. These aliquots are transferred periodically to the Framingham Heart Study Genetics Laboratory, at Boston University Medical Center.

Serum

1. Serum is used for Creatinine, Albumin, ALT and AST, which are measured daily in the FHS laboratory.
2. Serum is saved in several aliquots for future measurements; stored at -80 C.

CPT

CPT blood collection tubes are transferred daily to the Framingham Heart Study Genetics Laboratory at Boston University Medical Center. Peripheral blood mononuclear cells are isolated and cryopreserved for future generation of induced pluripotent stem cells and an immune response study.

Citrate

1. Citrate whole blood and plasma are used for platelet function testing, which is performed daily in the FHS laboratory.
2. Citrate plasma is saved in several aliquots for future measurements; stored at –80 C.

Hirudin

Hirudin whole blood is used for platelet function testing, which is performed daily in the FHS laboratory.

Urine [Random, spot urine]

1. Urine is used for pregnancy testing, which is performed daily in the FHS laboratory. Bone Study personnel identify the subset of female participants who require pregnancy testing.
2. Urine is saved in several aliquots for future measurements; stored at –80 C.



670 Albany Street
 2nd Floor
 Boston, MA 02118
 Tel: 617-638-6572
<http://www.bumc.bu.edu/stemcells/>

iPS CORE

Isolation of Peripheral Blood Mononuclear Cells (PBMCs) for Framingham Heart Study (FHS) Adult Participants

Induced pluripotent stem cells (iPSCs) can be generated from freshly collected or frozen PBMCs

- Clean venipuncture site and top of blood draw tube with 70% isopropyl alcohol pads
- Draw 4 mL of peripheral blood into one BD Vacutainer CPT Cell Preparation Tube (BD 362760). Invert tube 8-10x and keep upright at room temperature (RT).
 The CPT Vacutainers are barcoded and scanned into the FHS inventory tracking system. An excel file is created that serves as the daily shipping file that lists all specimens included in that day's delivery and is emailed for uploading into the inventory system of FHS Genetics Laboratory at Boston University Medical Center (BUMC)
- Samples are packaged according to Category B Biological Substances and are picked up and transported by Breakaway Courier Systems to Boston University Medical Center, FHS Genetics Laboratory, 75 E. Newton Street, Evans 301, Boston, MA 02118.
- Centrifuge samples at 1,800 RCF for 30 min at RT (ideally within 2 hrs of collection).
- Use a 1 mL pipet tip to collect buffy coat (cell layer between gel barrier and plasma) into a sterile 15 mL conical centrifuge tube and bring volume up to 10 mL with sterile PBS; invert several times.
- Centrifuge 300 RCF for 15 min and aspirate supernatant.
- Resuspend cell pellet in 10 mL of sterile PBS.
- Centrifuge 300 RCF for 10 min and aspirate supernatant.
- Resuspend cell pellet in 2 mL freezing medium (90% FBS/10% DMSO) and aliquot into 2 vials @1 mL/cryovial, ~ 2x10⁶ cells/vial. Typical yield is approx. 3-4x10⁶ cells in a 4 mL blood draw.
- Slow freeze vials at -80°C overnight and transfer to liquid nitrogen storage the following day.

Materials and reagents:

- Sterile Alcohol Prep Pads (Dynarex 1103; Medplusmedicalsupply.com; Model: DYN-1103)
- BD Vacutainer™ CPT™ Cell Preparation Tubes with Sodium Citrate; Manufacturer: BD 362760; Vendor, Fisher Scientific; http://www.bd.com/vacutainer/pdfs/bd_cpt_VDP40104.pdf
- Dulbecco's PBS (DPBS) (Fisher Cat # 14-190-144)
- FBS: Hyclone FBS Characterized (Cat # SH30071.03; LOT# AYF161496), 0.22 micron filtered
- CellTreat Filter systems (MedSupply Partners Cat # CT-229706; CT-229705)
- DMSO (Sigma Cat # D2650)
- Nalgene 2.0 mL cryovials (Fisher Cat # 03-337-7D)

Reference: Sommer AG, Rozelle SS, Sullivan S, Mills JA, Park SM, Smith BW, Iyer AM, French DL, Kotton DN, Gadue P, Murphy GJ, Mostoslavsky G. *J Vis Exp.* 2012 Oct 31;(68).

EXIT INTERVIEW PROCEDURES

During the exit interview (all staff):

1. Review the referral tracking sheet, MD Completeness and Tech Completeness screens. Review with the participant any referral recommendations.
2. Confirm with the participant that they have completed their Food Frequency Questionnaire and have given it to a FHS staff member.
3. Review that they have/have not participated in the eFHS study.
4. Explain and offer the Actical. If the participant takes the Actical, review the instructions with them.
5. Inform the participants about the Stool Microbiome Study and TBI Study.
6. Ask for feedback from the participant on how they felt about their examination.
7. Write in any comments that are made.
8. Make sure the participant leaves the Center area with all of their belongings; **ESPECIALLY THEIR MEDICATION BAG WITH MEDICATIONS.** Have the participant physically check their medications in front of you.
9. Read the disclaimer to the participant (on the Exit Interview screen):
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-ups with your physician or health care provider.
10. Give participant the reusable tote bag gift.
11. **THANK** the participant for their time and willingness to participate.

COMMONLY ASKED QUESTIONS

Q. When will you call me back for my next exam?

A. We can't say for sure right now. Investigators will begin planning for future exams as our current research contract with NHLBI is completed.

Q. What will be in my report and when will I get it?

A. You will receive your report in roughly 4-6 weeks. Your report will have results of your blood work, your blood pressure, a wallet-sized plastic copy of your ECG, a general statement from the physician who saw you, and a report from the exercise station.

Q. How many participants are involved in the FHS?

A. The original Cohort group had roughly 5200 in 1948. There are roughly about 40 of this group still living. We SAW about 2700 Offspring during Exam 9 and we plan to see about 3600 Generation 3 participants.

Exit Interview Supervisor Checklist

Yes	No	
		Review the referral tracking sheet, MD Completeness and Tech Completeness screens. Review with the participant any referral recommendations - Have participant check that their medications are all in the bag -Have/have not done eFHS -Offer Actical - Offer Microbiome Kit - Offer TBI brochure Enter correct responses into RedCap
		Confirm that ppt has completed FFQ or is taking it home
		Ask for any feedback from ppt on how they felt about their exam; write in comments
		Read disclaimer: <i>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-ups with your physician or health care provider.</i>
		Make sure ppt leaves with all belongings, especially medications.
		Give ppt gift
		Thank them for their time and willingness to participate
		Escort them out

**Call Backs/ Split Exams
Gen 3 Exam 3 Omni 2**

Participants Name / I.D :

Second Appointment Date:

Center Exam Date:

Recruiter's Initials:_____

***Check Box to indicate which test(s) will be completed on the second visit.**

TEST:	APPROXIMATE TIME:
<input type="checkbox"/> MD Questionnaire	40 Min.
<input type="checkbox"/> Anthropometry (Ht, Wt, Waist/Hip)	10 Min.
<input type="checkbox"/> Self-Administered Questionnaires	15 Min.
<input type="checkbox"/> Tech Administered Questions	15 Min.
<input type="checkbox"/> Cerad/Stroop	30 Min.
<input type="checkbox"/> Urine	5 Min.
<input type="checkbox"/> Lab	10 Min
<input type="checkbox"/> ECG	15 Min.
<input type="checkbox"/> Hand Grip	5 Min.
<input type="checkbox"/> Exercise Test (Fasting)	30 Min.
<input type="checkbox"/> Tonometry (Fasting)	20 Min
<input type="checkbox"/> Fibroscan (2 hr Fast)	15min
<input type="checkbox"/> Bone	20-30 min
<input type="checkbox"/> Accelerometer	10 min
<input type="checkbox"/> eFHS	20 min
<input type="checkbox"/> Stool Microbiome	10 Min.

- Why did this participant leave early?

Gen 3 Exam 3 Omni 2: Short Examination/Split Exam

A short exam is completed when a participant requests an abbreviated exam (usually up to 2 hours of testing). A split exam is completed when a participant requests to do an examination in 2 visits.

The priority of exam procedures is listed below:

I. Informed Consent & Tracking Procedures

- 1) Informed Consent
- 2) HIPPA-Release of Health Information for Research Purposes
- 3) Tracking Information Form

II. Clinical Measurements & Procedures

- 1) Lab
 - a. Blood
 - b. Urine
- 2) Anthropometrics
 - a. Weight
 - b. Height
 - c. Waist at Umbilicus
 - d. Hip
- 3) ECG

III. Physician-Administered Medical History and Physical Exam

- 1) Medical History
- 2) Resting Blood Pressure

If time permits for a short exam, the participant will undergo Tonometry, CPFE, and tech administered questionnaires.

If the participant chooses to have a split exam a second date will be arranged to complete all of the remaining testing for the exam cycle.

PROCEDURES FOR PARTICIPANTS THAT FAINT

- 1. If supine keep participant laying down**
- 2. If participant is sitting up, lower the head between the knees**
- 3. Center MD should be called in to evaluate the participant**
- 4. Put on BP cuff and take BP, Keep BP cuff on afterwards**
- 5. Apply an instant ice pack on the back of the neck and forehead**
- 6. Ask the participant if they have a history of fainting**
- 7. Offer the participant some water or juice**
- 8. The participant should remain stable for 15 minutes after the episode to recover**
- 9. Center MD should fill out the “Medical Encounter form**
- 10. Placed form inside participant chart as the first page**
- 11. Document incident as Adverse Event on the Exit Interview form**
- 12. Recruiting Manager will obtain a copy from RedCap**
- 13. Do not allow the participant to drive a car for at least 30 minutes post recovery**

Supervisor Observation Report
Individual Performance
Observation Date(s): _____
Meeting date: _____

	Supervisor ID #
	Tech ID #
	Quarter
<input type="checkbox"/> if yes fill in below	Did the tech perform any minor deviations? 0=No, 1=Yes, 9=Unknown
RESULT	
<input type="checkbox"/>	Number of minor deviations
AREA OF MINOR DEVIATION	
Check all the apply	<input type="checkbox"/> Anthropometry <input type="checkbox"/> ECG <input type="checkbox"/> AAD <input type="checkbox"/> Questionnaires <input type="checkbox"/> PFT <input type="checkbox"/> Observed Perf.
DEVIATION & CORRECTIVE ACTION	
	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>
<input type="checkbox"/>	Did the supervisor review minor deviations with tech? 0=No, 1=Yes, 9= Unknown

Definition:

Minor deviation: A non-serious departure from the standard protocol. A minor deviation does not affect data outcome. Examples: Handouts not being used, instructions not being given word for word

<input type="checkbox"/> if yes fill in below	Did the tech perform any major deviations? 0=No, 1=Yes, 9=Unknown
RESULT	
<input type="checkbox"/>	Number of major deviations
AREA OF MAJOR DEVIATION	
Check all the apply	<input type="checkbox"/> Anthropometry <input type="checkbox"/> ECG <input type="checkbox"/> AAD <input type="checkbox"/> Questionnaires <input type="checkbox"/> PFT <input type="checkbox"/> Observed Perf.
DEVIATION & CORRECTIVE ACTION	
	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>
<input type="checkbox"/>	Did the supervisor review major deviations with tech? 0=No, 1=Yes, 9= Unknown
/ /	Follow-up date to ensure major deviation is no longer performed. 0=No, 1=Yes, 9= Unknown

Definition:

Major deviation: A serious departure from the standard protocol. A major deviation does affect the outcome of data. Therefore requires supervisor follow-up. Examples: Leads crossed during ECG, leading question, improper placement of equipment.

COMMENTS	
	<p>Protocol areas not reviewed above:</p> <p>Other Notes:</p> <p>Overall Impression:</p> <p>Supervisor follow-up:</p> <p>Tech Feedback from Meeting:</p>

<input type="checkbox"/>	<p>Was a copy of this report given to technician? 0=No, 1=Yes, 9=Unknown</p>
<input type="checkbox"/>	<p>Was a copy of this report given to the clinic director? 0=No, 1=Yes, 9=Unknown</p>

Supervisor Signature:

Date:

Tech Signature:

Date:

**Supervisor Observation Report
Quarter Final Report -
Meeting Date:**

Cumulative Deviations Quarter
Total Number of Minor Deviations:
Total Number of Major Deviations:

MINOR DEVIATIONS	
Area of Deviation	

MAJOR DEVIATIONS	
Area of Deviation	

DEVIATION & CORRECTIVE ACTION	

Protocol for ECG Cards

We will be creating templates of the ECG for Gen 3 Exam 3. These templates will then be sent to Sir Speedy (in a sealed envelope) in which ECG cards are made. Sir Speedy will return the new ECG cards (in a sealed envelope) to FHS. The ECG cards are then given to Vicki Peterson to distribute to each participant. The invoice from Sir Speedy will be mailed to Peter Allen (treasurer of the Friends of FHS).

How to create labels for ECG cards:

You will need Avery #5161 white mailing labels 1" x 4"

Labels are placed in printer:

- Label side down
 - Top of label sheet goes into printer
1. Each ECG will have 2 white labels placed on top. The first label has the participant's first and last name, and is positioned on the top left side of the ECG (just above the red grid). The second label has the date of the ECG, and is positioned on the top right side of the ECG (just above the red grid).
 2. The ECGs are placed in a large white sealed FHS envelope. You will write on the envelope the total number of cards enclosed, as well as date's listed from the ECG. Also in this envelope is a return envelope for Sir Speedy to return the ECGs and cards. Label this envelope: Clinic. Under Clinic write the name of the person this should go to (ie: Emily).
 - a. Example: January 15, 2010 to January 20, 2010.
 3. Write "Sir Speedy" on the front of the envelope, and call them at 508-879-3277. Let them know that the FHS has a pick-up for them at the front desk.
 4. In the ECG cards/Sir Speedy white binder you will list the date order was sent to Sir Speedy and the total quantity of ECG cards to be made.
 5. Once the order has been returned to the FHS than please list in the binder the date ECG cards were returned, and any comments you may have.
 6. Keep the returned ECGs (paper copy) for ~ 6 months then shred. (The ECGs may be needed to make a lost/forgotten card/name change, etc.)

List of Ancillary Studies Conducted at Exam 3

The following ancillary studies were also conducted during the core exam.

1. Neurocognitive Questionnaires
 - a. CERAD-Stroop Questionnaires
 - b. Montreal Cognitive Assessment
 - c. AD8
2. Bone study
3. Tonometry
4. Cardiopulmonary Fitness Evaluation
5. eFHS
6. FibroScan
7. Traumatic Brain Injury Questionnaires
8. Platelet Aggregation
9. Accelerometer
10. Stool Microbiome
11. Food Frequency Questionnaire

Medical Encounters

1st Examiner ID

Since your last provided medical information have you had any of the following?

Desde la última vez que nos dió información médica ¿ha tenido lo siguiente?

Hospitalizations (not E.R.)? Hospitalizaciones, no emergencias?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
Hospitalization	
Reason / ¿Por qué razón?	Character field
Year / En que año?	4 digit year 9999 = Unknown
DATE details / Fecha? (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	Character field
Name of hospital / En qué hospital?	Character field
Location of hospital / Dónde?	Character field
Have you had another hospitalization? ¿Ha tenido otra hospitalización?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	

Block of questions ("Reason" to "Have you had another hospitalization") repeats 3 more times

E.R. visits only? ¿Ha ido sólo a emergencias?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
E.R. Visit	
Reason / ¿Por qué razón?	Character field
Year / En que año?	4 digit year 9999 = Unknown
DATE details / Fecha? (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	Character field
Name of hospital / En qué hospital?	Character field
Location of hospital / Dónde?	Character field
Have you had another E.R. visit? ¿Ha ido en otra ocasion a emergencias?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	

Block of questions ("Reason" to "Have you had another E.R. Visit") repeats 3 more times

Medical Encounters (cont-1)

Day surgery? ¿Cirugía saliendo el mismo día?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
Day Surgery	
Reason / ¿Por qué razón?	Character field
Year / En que año? 4 digit year	9999 = Unknown
DATE details / Fecha? (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	Character field
Name of hospital / En qué hospital?	Character field
Location of hospital / Dónde?	Character field
Have you had another day surgery? ¿Ha tenido otra cirugía saliendo el mismo día?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	

Block of questions ("Reason" to "Have you had another day surgery") repeats 3 more times

Major illness with visit to doctor? ¿Enfermedad grave con visita al doctor?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
Major Illness	
Reason / ¿Por qué razón?	Character field
Year / En que año? 4 digit year	9999 = Unknown
DATE details / Fecha? (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	Character field
Name of hospital / En qué hospital?	Character field
Location of hospital / Dónde?	Character field
Have you had another major illness with visit to doctor? ¿Ha tenido otra enfermedad grave con visita al doctor?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	

Block of questions ("Reason" to "Have you had another major illness with visit to doctor") repeats 3 more times

Medical Encounters (cont-2)

Checkup or office visit with doctor or other health care provider? ¿Chequeo con su doctor de cabecera?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
Checkup or office visit	
Reason / ¿Por qué razón?	Character field
Year / n que año? 4 digit year	9999 = Unknown
DATE details / Fecha? (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	Character field
Name of hospital / En qué hospital?	Character field
Location of hospital / Dónde?	Character field
Have you had another checkup or office visit with doctor or other health care provider? ¿Ha tenido otro chequeo con su doctor o proveedor de cuidados médicos	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	

Block of questions("Reason" to "Have you had another checkup or office visit with doctor or other health care provider")
repeats 3 more times

Additional Comments

Medical Encounters

Aspirin Aspirina

Do you take aspirin REGULARLY? ¿Toma aspirina REGULARMENTE?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
How many aspirin? ¿Cuántas aspirinas?	999 = Unknown
How often do you take this many aspirin? ¿Qué tan seguido las toma?	1 = Day 2 = Week 3 = Month 4 = Year 9 = Unknown
Usual dose of aspirin (mg)? ¿De cuántos miligramos?	81 = 81 mg - Baby 160 = 160 mg - Half 250 = 250 mg - e.g. Excedrin 325 = 325 mg - Usual 500 = 500 mg - Extra strength 888 = Other 999 = Unknown
If dose of aspirin is "Other"	Aspirin dose in mg

Diagnoses and Treatment Questions Preguntas de Diagnósticos y Tratamientos**High Blood Pressure or Hypertension Presión Arterial Alta o Hipertensión**

Have you been TOLD by your doctor you have high blood pressure or hypertension? ¿Le ha dicho un doctor que tiene la presión arterial alta, o hipertensión?	0 = No; 1 = Yes; 9 = Unknown
Are you CURRENTLY TAKING MEDICATION for high blood pressure or hypertension? ¿TOMA ACTUALMENTE MEDICINAS para la presión arterial alta o hipertensión?	0 = No; 1 = Yes; 9 = Unknown

High Blood Cholesterol or High Triglycerides Colesterol o Trigliceridos Elevados en la Sangre

Have you been TOLD by your doctor you have high blood cholesterol or high triglycerides? ¿Le ha dicho un doctor que tiene colesterol o trigliceridos elevados?	0 = No; 1 = Yes; 9 = Unknown
Are you CURRENTLY TAKING MEDICATION for high blood cholesterol or high triglycerides? ¿TOMA ACTUALMENTE MEDICINAS para el colesterol o trigliceridos elevados?	0 = No; 1 = Yes; 9 = Unknown

High Blood Sugar or Diabetes Azúcar Elevada en la Sangre o Diabetes

Have you been TOLD by your doctor you have high blood sugar or diabetes? ¿Le ha dicho un doctor que tiene diabetes o azúcar elevada en la sangre?	0 = No; 1 = Yes; 9 = Unknown
Are you CURRENTLY TAKING MEDICATION for high blood sugar or diabetes? ¿TOMA ACTUALMENTE MEDICINAS para la diabetes o azúcar elevada en la sangre?	0 = No; 1 = Yes; 9 = Unknown

Cardiovascular Disease Enfermedades Cardiovasculares

Are you CURRENTLY TAKING medication for cardiovascular disease? (for example angina/chest pain, heart failure, atrial fibrillation/heart rhythm abnormality, stroke, leg pain when walking, peripheral artery disease) ¿TOMA ACTUALMENTE medicinas para enfermedades cardiovasculares? (por ejemplo: angina/dolor en el pecho, fallo cardíaco, fibrilación auricular/anormalidad del ritmo cardíaco, embolia, dolor en las piernas cuando camina, enfermedad de las arterias periféricas)	0 = No; 1 = Yes; 9 = Unknown
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Additional Comments

Medications Medicamentos

As Directed by Physician or HCP Recetados por doctor

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? <b style="color: red;">En el último mes ¿ha tomado medicamentos recetados y no recetados por su doctor?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
Medication bag with medications brought to exam? <b style="color: red;">¿Trajo sus medicinas al examen?	0 = No; 1 = Yes
NOTE: For ASPIRIN ONLY - Do not code aspirin on this page. CODE ON PRIOR PAGE M03	
Medication name Select from drop down	Character field
Able to select up to 20 different medications	Character field
Are there any medications that you could not find on the drop down list?	0 = No; 1 = Yes
If "Yes"	
Medication name - not in drop down list	Character field
Add up to 20 different medications not from drop down list	Character field

Over the Counter Products (OTC) No recetados por doctor

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)? <b style="color: red;">¿Toma productos farmacéuticos NO RECETADOS por su doctor como vitaminas, suplementos, extractos o medicina alternativa?	0 = No; 1 = Yes; 9 = Unknown	
Please answer all over the counter questions below	0 = No	1 = Yes
Vitamins Vitaminas	<input type="checkbox"/>	<input type="checkbox"/>
Other Otros	<input type="checkbox"/>	<input type="checkbox"/>

Vaccinations

Have you received an influenza vaccine (aka "flu shot") within the last year? <b style="color: red;">En el último año ¿recibió la vacuna contra la influenza (flu shot)?	0 = No 1 = Yes 2 = Maybe 9 = Unknown
Have you ever received a pneumovaccine? <b style="color: red;">¿Alguna vez le han puesto la vacuna contra la pulmonía?	0 = No 1 = Yes 2 = Maybe 9 = Unknown

Additional Comments

Medications

Female Reproductive History - Pregnancy

Participant is male. Select "Save and go to Next Form"

Check here to confirm study participant is female. <input type="checkbox"/> Check box	1 = Yes, female
If "Yes"	
Pregnancy Embarazo	
Since your last exam have you taken or used birth control pills, shots, or hormone implants for birth control or medical indications (not post-menopausal hormone replacement)? Desde su último examen ¿ha tomado o usado métodos anticonceptivos como píldoras, inyecciones, implantes de hormonas por indicaciones médicas (no como tratamiento de reemplazo de hormonas post-menopáusicas)?	0 = No 1 = Yes, now 2 = Yes, not now 9 = Unknown
Have you ever tried to become pregnant for a year or more without becoming pregnant? ¿Ha tratado de quedar embarazada por un año o más sin resultados?	0 = No; 1 = Yes, 9 = Unknown
Have you ever used infertility treatment? ¿Alguna vez ha usado tratamiento para infertilidad?	0 = No; 1 = Yes, 9 = Unknown
Have you been pregnant since your last exam? ¿Ha estado embarazada desde su último examen?	0 = No; 1 = Yes, 9 = Unknown
If "Yes"	
Number of pregnancies? ¿Número de embarazos?	1 = One pregnancy 2 = Two pregnancies 3 = Three pregnancies 4 = Four pregnancies 5 = Five pregnancies 6 = Six pregnancies 7 = Seven pregnancies
During any of these pregnancies, were you told you had high blood pressure or hypertension? Durante alguno de sus embarazos ¿le dijeron que tenía presión arterial alta o hipertensión?	0 = No; 1 = Yes, 9 = Unknown
During any of these pregnancies, were you told you had eclampsia, pre-eclampsia (toxemia)? Durante alguno de sus embarazos ¿le dijeron que tenía eclampsia o pre-eclampsia (toxemia)?	0 = No; 1 = Yes, 9 = Unknown
During any of these pregnancies, were you told you had high blood sugar or diabetes? Durante alguno de sus embarazos ¿le dijeron que tenía diabetes o azúcar alta en la sangre?	0 = No; 1 = Yes, 9 = Unknown
Have you had any live births since your last exam? ¿Ha dado a luz desde su último examen?	0 = No; 1 = Yes
If "Yes"	
Number of live births since your last exam Número de partos vivos desde su último examen	1, One baby 2, Two babies 3, Three babies 4, Four babies

Questions about babies (born since last exam)**Preguntas sobre bebés (nacidos después de su último examen)**

Baby Bebé	
Full term? ¿A término completo?	0 = Less than 37 weeks 0 = Menos de 37 semanas 1 = 37 weeks or more 1 = 37 semanas o más 9 = Unknown Desconocido
Birth weight - (pounds) Peso al nacer – (libras)	99 = Unknown
Birth weight - (ounces) Peso al nacer – (onzas)	99 = Unknown
Did you breast feed? (include expressed breast milk) ¿Le dió pecho? (incluyendo leche succionada con aparato)	0 = No; 1 = Yes, 9 = Unknown
If "Yes"	
How long? ¿Por cuánto tiempo?	1 = Less than 6 weeks 1 = Menos de 6 semanas 2 = 6 to 11 weeks 2 = 6 a 11 semanas 3 = 3 to 6 months 3 = 3 a 6 meses 4 = More than 6 months 4 = Más de 6 meses 9 = Unknown Desconocido

Block of questions ("Full term?" to "How long?") **repeats 3 more times**

Additional Comments

Female Reproductive History - Pregnancy

Female Reproduction History - Menopause and Surgery

Participant is male. Select "Save and go to Next Form"

Check here to confirm study participant is female. <input type="checkbox"/> Check box		1 = Yes, female
If "Yes"		
Menopause		Menopausia
<p>What is the best way to describe your periods? (Check the BEST answer)</p> <p>¿Cómo describiría mejor sus períodos?</p>	<p>1 = Not stopped 2 = Periods stopped due to pregnancy, breast feeding, or hormonal contraceptive (for example: depo-provera, progestin releasing IUD, extended release birth control pill) 3 = 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 4 = Periods stopped for less than 1 year (premenopausal) 5 = Periods stopped for 1 year or more 6 = Periods stopped, but now have periods induced by hormones</p>	<p>1 = No han parado 2 = Pararon por embarazo, lactancia o anticonceptivos (como depo-provera, IUD de progestin, pastillas anticonceptivas de efecto prolongado) 3 = Pararon por bajo peso, ejercicio pesado o por medicación o condición de la salud como enfermedad de la tiroides, tumor en la pituitaria, imbalance hormonal, estrés 4 = Los períodos paran hace menos de un año (premenopausia) 5 = Los períodos pararon hace más de un año 6 = Los períodos pararon pero ahora los tiene de nuevo inducidos por hormonas.</p>
If selected 3 above		
Write in CAUSE why periods stopped ¿Por qué pararon sus períodos?		Character field
If selected 4 above		
NUMBER OF MONTHS since last period ¿Hace cuántos meses tuvo el ultimo período?		99 = Unknown
If selected 6 above		
NUMBER OF MONTHS periods stopped before hormones started ¿Por cuántos meses pararon sus períodos antes de que empezara con hormonas?		99 = Unknown
If selected 1 or 2 or 3 or 4 above		
WHEN was the first day of your last menstrual period? (If first day of last menstrual period is unknown, enter 1/1/1900) ¿Cuándo fue el primer día de su ultimo período?		1/1/1900 = Unknown
HOW MANY periods have you had in past 12 months? ¿Cuántos períodos ha tenido en los últimos 12 meses?		99 = Unknown
If selected 4 or 5 or 6 above		
AGE when periods stopped ¿Qué edad tenia cuando pararon? (If periods now induced by hormones, code age when periods naturally stopped. If perimenopausal, code age when periods stopped or became irregular.)		99 = Unknown

Female Reproduction History - Menopause and Surgery (cont)

<p>Was your menopause natural or the result of surgery, chemotherapy, or radiation? (If periods stopped for less than a year choose best answer.) Su menopausia, fué natural? O como resultado de cirugía, quimioterapia o radiación?</p>	<p>1 = Natural 2 = Surgical 3 = Chemo or radiation 4 = Other 9 = Unknown</p>
<p>Have you since your last exam taken HORMONE REPLACEMENT THERAPY (estrogen or progesterone) or a selective estrogen receptor modulator (such as <u>evista</u> or <u>raloxifene</u>)? Desde su último examen ¿ha tenido terapia de reemplazo de hormonas (estrógeno o progesterona) o modulador de receptor de estrógeno como evista o raloxifen?</p>	<p>0 = No 1 = Yes, now 2 = Yes, not now 9 = Unknown</p>

Surgery History Historial de Cirugías	
<p>Since your last exam have you had a hysterectomy (uterus or womb removed)? Desde su último examen ¿ha tenido histerectomía (el útero o matriz removidos)?</p>	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
Age at hysterectomy? ¿A qué edad lo tuvo?	99=Unknown
Date of hysterectomy – Year ¿En qué año?	2002-2021; 9999 = Unknown
Date of hysterectomy – Month ¿Mes?	1-12; 99 = Unknown
<p>Since your last exam have you had an operation to remove one or both of your ovaries? Desde su último examen ¿le han removido uno o ambos ovarios?</p>	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
Age when ovaries removed? ¿A qué edad? (If more than one surgery, use age <u>at last surgery</u> .)	99=Unknown
<p>Number of ovaries removed? ¿Cuántos le removieron?</p>	<p>1 = One ovary 2 = Two ovaries 4 = Part of an ovary 3 = Unknown number of ovaries</p>

Additional Comments

Female Reproduction History - Menopause and Surgery

Cigarettes Cigarros

Since your last exam have you smoked cigarettes regularly? Desde su último examen ¿ha fumado cigarros regularmente?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
Have you smoked cigarettes regularly in the LAST YEAR? ¿Ha fumado cigarros regularmente en el ULTIMO AÑO?	0 = No or less than 1 cigarette a day per year No o menos de 1 cigarro al año 1 = Yes 9 = Unknown
Do you now smoke cigarettes (as of 1 month ago)? De un mes para acá ¿ha fumado cigarros?	0 = No; 1 = Yes; 9 = Unknown
How many cigarettes do you smoke per day now? ¿Cuántos cigarros fuma ahora al día?	99 = Unknown
Questions below refer to "whole lifetime" Las siguientes preguntas se refieren a "lo largo de su vida"	
On the average of the entire time you smoked, how many cigarettes did you smoke per day? En promedio del tiempo que fumó ¿cuántos cigarros fumaba al día?	99 = Unknown
How old were you when you first started regular cigarette smoking? ¿Cuántos años tenia cuando empezó a fumar cigarros regularmente?	99 = Unknown
If you have stopped smoking cigarettes completely, how old were you when you stopped? Si dejó de fumar cigarros por completo ¿cuántos años tenia?	00 = Not stopped No ha parado 99 = Unknown
When you were smoking, did you ever stop smoking for more than 6 months? Cuando estaba fumando ¿alguna vez dejó de fumar por más de 6 meses?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
For how many years in total did you stop smoking cigarettes? ¿Por cuántos años en total dejó de fumar cigarros?	# of years # de años 1 = 6 months - 12 months 6 meses - 12 meses 99 = Unknown

Pipes or Cigars Pipas o Puros

Since your last exam have you regularly smoked a pipe or cigar? Desde su último examen ¿ha fumado regularmente pipa o puro?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
Do you smoke a pipe or cigar now? ¿Fuma ahora pipa o puros?	0 = No; 1 = Yes; 9 = Unknown

E-cigarettes Cigarros Electrónicos

E-cigarettes are battery-powered and produce vapor instead of smoke. Los cigarros electrónicos se encienden con batería y producen vapor en lugar de humo	
Have you ever tried an e-cigarette? ¿Ha probado cigarros electrónicos?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
Have you ever been a regular user of e-cigarettes? ¿Usa regularmente cigarros electrónicos? (at least once per week) (al menos 1 por semana)	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
How long did you use e-cigarettes? – months ¿Por cuánto tiempo usó cigarros electrónicos? - meses	999 = Unknown
How many days per week, on average, did you use e-cigarettes while you were a regular user? En promedio ¿cuántos días a la semana usó cigarros electrónicos cuando los usó regularmente?	# of days per week # de días por semana 1 = 1 day or less per week 1 día o menos por semana 9 = Unknown
In the past 5 days, including today, on how many days did you smoke an e-cigarette? En los últimos 5 días ¿cuántos de esos días fumó cigarros electrónicos?	0 = 0 days 0 días 1 = 1 day 1 día 2 = 2 days 2 días 3 = 3 days 3 días 4 = 4 days 4 días 5 = 5 days 5 días 7 = Refused to answer Rehusó contestar 9 = Don't know

Additional Comments

Smoking

Now I will ask you questions regarding your alcohol use.

Ahora le preguntaré sobre consumo de alcohol

Do you drink beer at least once a month? <small>(serving 12 oz. bottle, glass, can)</small> ¿Toma cerveza por lo menos una vez al mes? <small>(botella, vaso o lata -12 onzas)</small>	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
Do you drink beer at least once week? ¿Toma cerveza por lo menos una vez a la semana?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
Number of beers per week Número de cervezas por semana	999 = Unknown
If "No"	
Number of beers per month Número de cervezas al mes	999 = Unknown
Do you drink wine at least once a month? <small>(serving red or white, 4oz. glass)</small> ¿Toma vino por lo menos una vez al mes? <small>(copa o vaso de 4 onzas)</small>	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
Do you drink wine at least once a week? ¿Toma vino por lo menos una vez a la semana?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
Number of glasses of wine per week Número de copas de vino por semana	999 = Unknown
If "No"	
Number of glasses of wine per month Número de copas de vino al mes	999 = Unknown
Do you drink liquor or spirits at least once a month? <small>(serving 1 oz. cocktail or highball)</small> ¿Toma licor u otras bebidas alcohólicas por lo menos una vez al mes? <small>(cantidad: 1 onza)</small>	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
Do you drink liquor or spirits at least once per week? ¿Toma licor u otras bebidas alcohólicas por lo menos 1 vez a la semana?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
Do you drink liquor or spirits at least once per week? Número de bebidas de licor por semana	0 = No; 1 = Yes; 9 = Unknown
If "No"	
Number of liquor or spirit drinks per month Número de bebidas de licor al mes	999 = Unknown
At what age did you stop drinking alcohol? ¿A qué edad dejó de tomar alcohol? <small>00 = IF NOT STOPPED 888 = NEVER DRINKER</small>	<small>00 = If not stopped 888 = Never drinker 999 = Unknown</small>

Alcohol Consumption (cont)

<p>Over the past year, on average, on how many days per week did you drink an alcoholic beverage of any type? En el último año, en promedio ¿cuántos días a la semana toma alcohol de cualquier tipo?</p>	<p>0 = No days 1 = 1 day or less 9 = Unknown</p>
<p>Over the past year, on a typical day when you drink, how many drinks do you have? En el último año, en un día típico cuando toma ¿cuántas bebidas toma?</p>	<p>0 = No drinks 1 = 1 or less 99 = Unknown</p>
<p>What was the maximum number of drinks you had in a 24 hour period during the past month? ¿Cuál fue el máximo número de bebidas que tomó en un lapso de 24 horas en el último mes?</p>	<p>0 = No drinks 1 = 1 or less 99 = Unknown</p>
<p>Since your last exam has there been a time when you drank 5 or more alcoholic drinks of any kind almost daily? Desde su último examen ¿hubo alguna época en la que tomó más de 5 bebidas alcohólicas de cualquier tipo casi todos los días?</p>	<p>0 = No; 1 = Yes; 9 = Unknown</p>
<p>Examiner Opinion: Over the past year, does participant report drinking less than one alcoholic drink of any type per month? <small>(include current non-drinkers)</small></p>	<p>check box 1 = Yes</p>

Additional Comments

Alcohol Consumption

Cough Tos

Do you usually have a cough? - Exclude clearing of the throat	¿Tose usualmente? - No para aclarar la garganta	0 = No; 1 = Yes; 9 = Unknown
Do you usually have a cough at all on getting up or first thing in the morning? ¿Tose por la mañana al levantarse?		0 = No; 1 = Yes; 9 = Unknown
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? ¿Tosió así la mayoría de los días por tres o más meses consecutivos el último año?		0 = No; 1 = Yes; 9 = Unknown
How many years have you had this cough? ¿Cuántos años ha tenido esta tos?		Number of years 1 = 1 year or less 99 = Unknown

Phlegm Flemas

Do you usually bring up phlegm from your chest? ¿Saca flemas desde el pecho?		0 = No; 1 = Yes; 9 = Unknown
Do you usually bring up phlegm at all on getting up or first thing in the morning? ¿Saca flemas al levantarse por la mañana?		0 = No; 1 = Yes; 9 = Unknown
If "Yes" to either of the two questions directly above		
Do you bring up phlegm from your chest on most days for three consecutive months or more during the year? ¿Sacó flemas desde el pecho la mayoría de los días por tres o más meses consecutivos el último año?		0 = No; 1 = Yes; 9 = Unknown
How many years have you had trouble with phlegm? ¿Cuántos años ha tenido esto de las flemas?		Number of years 1 = 1 year or less 99 = Unknown

Wheeze Jadeos (tipo asma)

In the past 12 months... En los últimos 12 meses....		
Have you had wheezing or whistling in your chest at any time? ¿Ha tenido jadeos o silbidos desde el pecho en algún momento?		0 = No; 1 = Yes; 9 = Unknown
If "Yes"		
How often have you had this wheezing or whistling? ¿Qué tan seguido ha tenido esto?		1 = MOST days or nights 2 = A few days or nights a WEEK 3 = A few days or nights a MONTH 4 = A few days or nights a YEAR or less 9 = Unknown
Have you had this wheezing or whistling in the chest when you had a cold? ¿Ha tenido este problema cuando tiene resfriado?		0 = No; 1 = Yes; 9 = Unknown
Have you had this wheezing or whistling in the chest apart from colds? ¿Ha tenido este problema cuando no tiene resfriado?		0 = No; 1 = Yes; 9 = Unknown
Have you had an attack of wheezing or whistling in the chest that made you feel short of breath? ¿Ha tenido un ataque de jadeos o silbidos en el pecho que lo dejó corto de respiración?		0 = No; 1 = Yes; 9 = Unknown

Additional Comments

Sleep Related Symptoms (days/ nights) Síntomas Relacionados con el Sueño (días/noches)

In the past 12 months.... En los últimos 12 meses....	
On average how many nights a week did you snore? En promedio ¿cuántas noches a la semana roncó?	0 = Never Nunca 1 = Rarely (1-2 nights/week) Raramente (1-2 noches por semana) 2 = Occasionally (3-4 nights/week) Ocasionalmente (3-4 noches por semana) 3 = Frequently (5 or more nights/week) Frecuentemente (5 o más noches por semana) 8 = I don't know No sé 9 = Unknown Desconocido
On average, how many nights a week do you snort, gasp, or stop breathing while you are asleep? En promedio ¿cuántas noches a la semana resopla, jadea o deja de respirar durante la noche?	0 = Never Nunca 1 = Rarely (1-2 nights/week) Raramente (1-2 noches por semana) 2 = Occasionally (3-4 nights/week) Ocasionalmente (3-4 noches por semana) 3 = Frequently (5 or more nights/week) Frecuentemente (5 o más noches por semana) 8 = I don't know No sé 9 = Unknown Desconocido
On average, how many days a week have you had excessive (too much) daytime sleepiness? En promedio ¿cuántos días a la semana ha tenido excesivo sueño durante el día?	0 = Never Nunca 1 = Rarely (1-2 nights/week) Raramente (1-2 noches por semana) 2 = Occasionally (3-4 nights/week) Ocasionalmente (3-4 noches por semana) 3 = Frequently (5 or more nights/week) Frecuentemente (5 o más noches por semana) 8 = I don't know No sé 9 = Unknown Desconocido

Nocturnal Chest Symptoms Síntomas Nocturnos del Pecho

Since your last exam . . . Desde su último examen . . .	
Have you been awakened by shortness of breath? ¿Se ha despertado por falta de respiración?	0 = No; 1 = Yes; 9 = Unknown
Have you been awakened by coughing? ¿Se ha despertado por toser?	0 = No; 1 = Yes; 9 = Unknown

Shortness of Breath Falta de Respiración

Since your last exam . . . Desde su último examen . . .	
Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill? ¿Experimenta falta de aliento cuando camina de prisa a nivel plano o cuando sube una pequeña colina?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
Do you have to walk slower than people of your age on level ground because of shortness of breath? ¿Tiene que caminar más lento que otros de su edad por falta de aliento?	0 = No; 1 = Yes; 9 = Unknown
Do you have to stop for breath when walking at your own pace on level ground? Cuando camina normalmente a nivel plano ¿tiene que pararse para tomar el aliento?	0 = No; 1 = Yes; 9 = Unknown
Do you have to stop for breath after walking 100 yards (or after a few minutes) on level ground? Después de caminar 100 metros a nivel plano ¿tiene que pararse a tomar la respiración?	0 = No; 1 = Yes; 9 = Unknown
Do you or have you needed to sleep on two or more pillows to help you breathe (orthopnea)? ¿Tiene o ha tenido que dormir con dos almohadas para ayudarse a respirar (ortopnea)?	0 = No; 1 = Yes; 9 = Unknown

Have you had swelling in both your ankles (ankle edema)? ¿Ha tenido hinchazón en ambos tobillos (edema del tobillo)?	0 = No; 1 = Yes; 9 = Unknown
Have you been told by your doctor you had heart failure or congestive heart failure? ¿Le ha diagnosticado algún doctor con fallo cardiaco o fallo cardiaco congestivo?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
Have medical encounter details been entered on M01 Medical Encounters? ¿Ya me dió los detalles de ésta visita al doctor al principio?	0 = No; 1 = Yes
If "No"	
Name of doctor Nombre del doctor	Character field
Location of doctor Lugar donde se encuentra el doctor	Character field
Date of visit – year Fecha de la visita – año	9999 = Unknown
DATE details Detalles de la fecha (ej. abril, verano, etc.) (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	Character field
Have you been hospitalized or visited the E.R. for heart failure? ¿Ha sido hospitalizado o ido a emergencias por fallo cardiaco?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
Have medical encounter details been entered on M01 Medical Encounters? ¿Ya me dió los detalles de ésta visita al doctor al principio?	0 = No; 1 = Yes
If "No"	
Name of doctor Nombre del doctor	Character field
Location of doctor Lugar donde se encuentra el doctor	Character field
Date of visit – year Fecha de la visita – año	9999 = Unknown
DATE details Detalles de la fecha (ej. abril, verano, etc.) (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	Character field

CHF First Examiner Opinion

First Examiner believes CHF	0 = No 1 = Yes 2 = Maybe 9 = Unknown
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Additional Comments

Sleep Apnea and CHF Opinion

Le voy a tomar la presión arterial...

BP cuff size	0 = Pediatric 1 = Regular adult 2 = Large adult 3 = Thigh 9 = Unknown
Protocol modification	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
Comments for protocol modification	Character field
Systolic (to nearest 2 mmHg)	999 = Unknown
Diastolic (to nearest 2 mmHg)	999 = Unknown

Additional Comments

Blood Pressure 1st MD Reading

Since you last provided medical information...

Desde la última vez que nos dió información médica...

Have you experienced any CHEST DISCOMFORT? ¿Ha experimentado alguna MOLESTIA EN EL PECHO?	0 = No; 1 = Yes; 2 = Maybe; 9 = Unknown			
If "Yes" or "Maybe"				
<i>In addition to answering the questions, provide narrative comments in box below.</i>				
Chest discomfort with exertion or excitement ¿Le sucede cuando está exhausto o sobresaltado?	0 = No; 1 = Yes; 2 = Maybe; 9 = Unknown			
Chest discomfort when quiet or resting ¿Le sucede cuando está tranquilo o descansando?	0 = No; 1 = Yes; 2 = Maybe; 9 = Unknown			
Chest Discomfort Characteristics				
Date of onset – year ¿Cuándo le sucedió? ¿En qué año?	2002-2021, 9999 = Unknown			
DATE details ¿En qué fecha? (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	Character field			
Usual duration (minutes) ¿Cuánto tiempo le duró? minutos	1 = 1 min or less 900 = 15 hrs or more 999 = Unknown			
Longest duration (minutes) ¿Cuánto es lo más largo que ha durado? minutos	1 = 1 min or less 900 = 15 hrs or more 999 = Unknown			
Location ¿En qué parte del pecho?	0 = No 1 = Central sternum and upper chest 2 = Left upper quadrant 3 = Left lower ribcage 4 = Right chest 5 = Other			
Radiation ¿Radió hacia otros lados?	0 = No 1 = Left shoulder or left arm 2 = Neck 3 = Right shoulder or right arm 4 = Back 5 = Abdomen 6 = Other 7 = Combination 9 = Unknown			
Number of episodes of chest pain in past month Número de episodios en el último mes	999 = Unknown			
Number of episodes of chest pain in past year Número de episodios en el último año	999 = Unknown			
Type ¿Qué tipo de molestia fué?	1 = Pressure, heavy, vise Pesado, como presión 2 = Sharp Agudo 3 = Dull Ligero 4 = Other Otro 9 = Unknown Desconocido			
One choice per line	0 = No	1 = Yes	8 = Not tried	9 = Unknown
Relief by nitroglycerin in < 15 minutes ¿Se sintió mejor con nitroglicerina en menos de 15 minutos?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Relief by rest in < 15 minutes ¿Se sintió mejor descansando por menos de 15 minutos?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Relief spontaneously in < 15 minutes ¿Se sintió mejor de repente en menos de 15 minutos?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Relief by other cause in < 15 minutes ¿Se sintió mejor por otra cosa en menos de 15 minutos?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Since you last provided medical information...

Desde la última vez que nos dió informaci3n médica...

Have you been told by a doctor you had a heart attack, myocardial infarction or angina? ¿Le ha diagnosticado un doctor con ataque al coraz3n, infracci3n del miocardio o angina?	0 = No; 1 = Yes; 2 = Maybe; 9 = Unknown
If "Yes" or "Maybe"	
Have medical encounter details been entered on M01 Medical Encounters? ¿Ya me dió los detalles de ésta visita al doctor al principio?	0 = No; 1 = Yes
If "No"	
Name of doctor Nombre del doctor	Character field
Location of doctor Lugar donde se encuentra el doctor	Character field
Date of visit – year Fecha de la visita – a1o	2002-2021, 9999 = Unknown
DATE details Detalles de la fecha (ej. abril, verano, etc.) (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	Character field

Since you last provided medical information...

Have you been to a hospital or visited the ER for a heart attack, myocardial infarction or angina? ¿Ha ido al hospital o a emergencias por un ataque al coraz3n, infracci3n del miocardio o angina de pecho?	0 = No; 1 = Yes; 2 = Maybe; 9 = Unknown
If "Yes" or "Maybe"	
Have medical encounter details been entered on M01 Medical Encounters? ¿Ya me dió los detalles de ésta visita al doctor al principio?	0 = No; 1 = Yes
If "No"	
Name of hospital Nombre del hospital	Character field
Location of hospital Lugar del hospital	Character field
Date of visit – year Fecha de la visita – a1o	2002-2021, 9999 = Unknown
DATE details Detalles de la fecha (ej. abril, verano, etc.) (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	Character field

CHD First Examiner Opinions

Angina pectoris Angina de pecho	0 = No; 1 = Yes; 2 = Maybe; 9 = Unknown
If "Yes" or "Maybe"	
Angina pectoris since revascularization procedure?	0 = No; 1 = Yes; 2 = Maybe; 9 = Unknown
Coronary insufficiency	0 = No; 1 = Yes; 2 = Maybe; 9 = Unknown
Myocardial infarct	0 = No; 1 = Yes; 2 = Maybe; 9 = Unknown

Additional Comments

Atrial Fibrillation**Fibrilación Auricular****Since your last provided medical information****Desde la última vez que nos dió información médica**

Have you been told you have or have had atrial fibrillation (or atrial flutter)?
¿Ha tenido o le han dicho que ha tenido fibrilación auricular?

0 = No
 1 = Yes
 2 = Maybe
 9 = Unknown

If "Yes" or "Maybe"

Year of first episode Año del primer episodio	2002-2021, 9999 = Unknown
DATE details of first episode Detalles de fecha del 1er episodio (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	Character field
Hospitalized, ER or saw M.D. ¿Lo hospitalizaron o fue a emergencias o vió al doctor?	0 = No 1 = Hospitalized or ER 2 = Saw M.D. 9 = Unknown
If "Hospitalized or ER" or "Saw M.D."	
Have medical encounter details been entered on M01 Medical Encounters? ¿Ya me dió los detalles de ésta visita al doctor al principio?	0 = No; 1 = Yes
If "No"	
Name of hospital Nombre del hospital	Character field
Location of hospital Lugar del hospital	Character field
Name of doctor Nombre del doctor	Character field
Location of doctor Lugar donde se encuentra el doctor	Character field
Date of visit – year Fecha de la visita – año	2002-2021, 9999 = Unknown
DATE details Detalles de la fecha (ej. abril, verano, etc.) (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	Character field

Syncope**Síncope****Since your last exam ...****Desde su último examen ...**

Have you fainted or lost consciousness?
 (If event immediately preceded by head injury or accident, code as "No")
¿Se ha desmayado o ha perdido la conciencia?
(¿Por lesión de cabeza o por accidente? code as "No")

0 = No
 1 = Yes
 2 = Maybe
 9 = Unknown

If "Yes" or "Maybe"

Year of first episode Año del primer episodio	2002-2021, 9999 = Unknown
DATE details of first episode Detalles de fecha del 1er episodio (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	Character field
Number of episodes in the past two Número de episodios en los últimos 2 años	999=Unknown
Usual duration of loss of consciousness – minutes Duración usual de pérdida de la conciencia en minutos	1=1 min or less; 999=Unknown
Did you have any injury caused by the event? ¿Tuvo alguna lesión causada por esto?	0 = No 1 = Yes 2 = Maybe 9 = Unknown

Hospitalized, ER or saw M.D. for fainting or loss of consciousness ¿Lo han hospitalizado o a ido a emergencias o visto al doctor por pérdida de la conciencia?	0, No 1, Hospitalized or ER 2, Saw M.D. 9, Unknown
If "Hospitalized or ER" or "Saw M.D."	
Have medical encounter details been entered on M01 Medical Encounters? ¿Ya me dió los detalles de ésta visita al doctor al principio?	0 = No; 1 = Yes
If "No"	
Name of hospital Nombre del hospital	Character field
Location of hospital Lugar del hospital	Character field
Name of doctor Nombre del doctor	Character field
Location of doctor Lugar donde se encuentra el doctor	Character field
Date of visit – year Fecha de la visita – año	2002-2021, 9999 = Unknown
DATE details Detalles de la fecha (ej. abril, verano, etc.) (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	Character field
Have you had a head injury with loss of consciousness? ¿Ha tenido alguna lesion en la cabeza con pérdida de conciencia?	0 = No 1 = Yes 2 = Maybe 9 = Unknown
If "Yes" or "Maybe"	
Have medical encounter details been entered on M01 Medical Encounters? ¿Ya me dió los detalles de ésta visita al doctor?	0 = No; 1 = Yes
If "No"	
Year Año	2002-2021, 9999 = Unknown
DATE details Detalles de fecha (ej. abril, verano, etc.) (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	Character field
Have you had a seizure? ¿Ha tenido una convulsión?	0 = No 1 = Yes 2 = Maybe 9 = Unknown
If "Yes" or "Maybe"	
Year of most recent seizure Año de su mas reciente convulsión	2002-2021, 9999 = Unknown
DATE details Detalles de fecha (ej. abril, verano, etc.) (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	Character field
Hospitalized, ER or saw M.D. ¿Lo hospitalizaron o fue a emergencas o al doctor por esto?	0 = No 1 = Hospitalized or ER 2 = Saw M.D. 9 = Unknown
If "Hospitalized or ER" or "Saw M.D."	
Have medical encounter details been entered on M01 Medical Encounters? ¿Ya me dió los detalles de ésta visita al doctor al principio?	0 = No; 1 = Yes
If "No"	
Name of hospital Nombre del hospital	Character field
Location of hospital Lugar del hospital	Character field

Name of doctor Nombre del doctor	Character field
Location of doctor Lugar donde se encuentra el doctor	Character field
Date of visit – year Fecha de la visita – año	2002-2021, 9999 = Unknown
DATE details Detalles de la fecha (ej. abril, verano, etc.) (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	Character field

Are you being treated for a seizure disorder? ¿Le han dado tratamiento para convulsiones?	0 = No 1 = Yes 2 = Maybe 9 = Unknown
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Syncope First Examiner Opinion

Syncope	0 = No 1 = Yes 2 = Maybe 3 = Presyncope 9 = Unknown
If “Yes” or “Maybe”	
Cardiac syncope	0 = No 1 = Yes 2 = Maybe 9 = Unknown
Vasovagal syncope	0 = No 1 = Yes 2 = Maybe 9 = Unknown
Other syncope	0 = No 1 = Yes 2 = Maybe 9 = Unknown
If “Yes” or “Maybe”	
Specify other syncope	Character field

Additional Comments

Atrial Fibrillation, Syncope & Syncope Opinion

Cerebrovascular Disease Enfermedades Cerebrovasculares

Since you last provided medical information have you had Desde la última vez que nos dió información médica, ha tenido...				
One choice per line	0 = No	1 = Yes	2 = Maybe	9 = Unknown
Sudden muscular weakness Debilidad muscular repentina	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sudden speech difficulty Dificultad repentina para hablar	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sudden visual defect Defecto visual repentino	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sudden double vision Visión doble repentina	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sudden loss of vision in one eye Pérdida de la vision de un ojo repentinamente	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sudden numbness, tingling Hormigueo o adormecimiento repentinios	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If "Yes" or "Maybe"				
Numbness and tingling is positional ¿El adormecimiento y hormigueo es posicional?			0 = No 1 = Yes 2 = Maybe 9 = Unknown	
HEAD CT scan OTHER THAN FOR THE FHS Ha tenido un CT Scan de la cabeza -no como parte de su participación en FHS			0 = No 1 = Yes 2 = Maybe 9 = Unknown	
If "Yes" or "Maybe"				
Have medical encounter details been entered on M01 Medical Encounters? ¿Ya me dió los detalles de ésta visita al doctor al principio?			0 = No; 1 = Yes	
If "No"				
Name of facility Nombre de la clínica u hospital			Character field	
Location of facility Lugar			Character field	
Date - year Fecha - año			2002-2021, 9999 = Unknown	
DATE details Detalles de la fecha (ej. abril, verano, etc.) (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)			Character field	
HEAD MRI scan OTHER THAN FOR THE FHS Le han hecho un MRI de la cabeza -no como parte de su participación en FHS			0 = No 1 = Yes 2 = Maybe 9 = Unknown	
If "Yes" or "Maybe"				
Have medical encounter details been entered on M01 Medical Encounters? ¿Ya me dió los detalles de ésta visita al doctor al principio?			0 = No; 1 = Yes	
If "No"				
Name of facility Nombre de la clínica u hospital			Character field	
Location of facility Lugar			Character field	
Date - year Fecha - año			2002-2021, 9999 = Unknown	

DATE details Detalles de la fecha (ej. abril, verano, etc.) (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)		Character field			
Seen by neurologist ¿Ha visto a un neurólogo?		0 = No 1 = Yes 2 = Maybe 9 = Unknown			
If "Yes" or "Maybe"					
Have medical encounter details been entered on M01 Medical Encounters? ¿Ya me dió los detalles de ésta visita al doctor al principio?		<input type="checkbox"/>		0 = No; 1 = Yes	
If "No"					
Name of doctor Nombre del neurólogo		Character field			
Location of doctor Lugar donde se encuentra el neurólogo		Character field			
Date of visit – year Fecha de la visita – año		2002-2021, 9999 = Unknown			
DATE details Detalles de la fecha (ej. abril, verano, etc.) (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)		Character field			
One choice per line		0 = No	1 = Yes	2 = Maybe	9 = Unknown
Have you been told by a doctor you had a STROKE or TIA (transient ischemic attack, mini-stroke)? ¿Le ha dicho un doctor que tuvo un accidente cerebrovascular o ataque isquémico transitorio?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Have you been told by a doctor you have PARKINSON'S disease ? ¿Le ha dicho un doctor que tiene la enfermedad de Parkinson?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Have you been told by a doctor you have MEMORY problems, DEMENTIA or ALZHEIMER'S disease? ¿Le ha dicho un doctor que tiene problemas de Memoria, Demencia o Alzheimer's?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you feel or do other people think that you have memory problems that PREVENT you from doing things you've done in the past? ¿Usted u otras personas piensa que usted tiene problemas de memoria al grado que lo previene hacer cosas que hacía antes?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you feel your memory is becoming WORSE ? ¿Piensa que su memoria está EMPREORANDO?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Cerebrovascular Disease First Examiner Opinion

TIA or STROKE took place		0 = No 1 = Yes 2 = Maybe 9 = Unknown			
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.)		Character field			
Observed by		Character field			

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, ER or saw M.D.	0, No 1, Hospitalized or ER 2, Saw M.D. 9, Unknown
If "Hospitalized or ER" or "Saw M.D."	
Have medical encounter details been entered on M01 Medical Encounters?	0 = No; 1 = Yes
If "No"	
Name of hospital	Character field
Location of hospital	Character field
Name of doctor	Character field
Location of doctor	Character field
Date - year	2002-2021, 9999 = Unknown
DATE details (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	Character field

Additional Comments

Cerebrovascular Disease and Opinion

Venous and Peripheral Arterial Disease and Intermittent Claudication Opinion

Venous Disease **Enfermedades de las Venas**

Since you last provided medical information have you had Desde la última vez que nos dió información médica, ha tenido...	
Deep vein thrombosis - DVT (blood clots in legs or arms) ¿Trombosis de vena profunda (coágulos en brazos o piernas)?	0 = No 1 = Yes 2 = Maybe 9 = Unknown
Pulmonary embolus - PE (blood clot in lungs) ¿Embolismo Pulmonar (coágulos en el pulmón)?	0 = No 1 = Yes 2 = Maybe 9 = Unknown

Peripheral Arterial Disease

Since you last provided medical information have you had Desde la última vez que nos dió información médica, ha tenido...	
Do you get discomfort in either leg on walking? ¿Siente molestia en cualquiera de las piernas mientras camina?	0= No; 1 = Yes; 9 = Unknown
If "Yes"	
Does this discomfort ever begin when you are standing still or sitting? ¿La molestia ha empezado aún estando parado o sentado?	0= No; 1 = Yes; 9 = Unknown
When walking at an ordinary pace on level ground, how many city blocks until symptoms develop? (where 10 blocks = 1 mile) Caminando a su paso normal en nivel plano, ¿cuántas cuadras puede caminar antes que aparezcan molestias?	0 = more than 98 blocks required to develop symptoms 1 = 1 block or less 99 = Unknown
Claudication Symptoms	
Discomfort while walking... Molestias mientras camina...	
One choice per line	0 = No 1 = Yes 9 = Unknown
CALF – left PIERNA - izquierda	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
CALF – right PIERNA - derecha	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
NOT CALF – left lower extremity	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
NOT CALF – right lower extremity	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
If "Yes" discomfort NOT CALF - left or right	
Write in site of discomfort	Character field
Occurs with first steps (code worse leg) ¿Sucede en los primeros pasos?	0= No; 1 = Yes; 9 = Unknown
Do you get the discomfort when you walk up a hill or hurry? ¿Tiene molestias cuando camina de prisa o cuesta arriba?	0= No; 1 = Yes; 9 = Unknown
Does the discomfort ever disappear while you are still walking? ¿Han desaparecido las molestias mientras sigue caminando?	0= No; 1 = Yes; 9 = Unknown

Intermittent Claudication Opinion (cont)

What do you do if you get discomfort when you are walking? ¿Qué hace para que desaparezcan las molestias?	1 = Stop Se detiene 2 = Slow down Camina despacio 3 = Continue at same pace Contiúa igual
Time for discomfort to be relieved by stopping (minutes) ¿En cuántos minutos se siente mejor cuando se detiene?	0 = No relief with stopping 999 = Unknown
Number of days per month of lower limb discomfort ¿Cuántos días al mes tiene molestias en las piernas?	1 = 1 day/month or less 99 = Unknown
Since your last exam have you been told by a doctor you have intermittent claudication or peripheral artery disease? ¿Le ha diagnosticado un doctor con claudicación intermitente o enfermedad de las arterias periferias?	0= No; 1 = Yes; 9 = Unknown
If "Yes"	
Have medical encounter details been entered on M01 Medical Encounters? ¿Me dió los detalles de ésta visita al doctor al principio?	0 = No; 1 = Yes
If "No"	
Name of doctor Nombre del doctor	Character field
Location of doctor Lugar donde se encuentra el doctor	Character field
Date of visit – year Fecha de la visita – año	2002-2021, 9999 = Unknown
DATE details Detalles de la fecha (ej. abril, verano, etc.) (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)	Character field
Since your last exam have you been told by a doctor you have spinal stenosis?	2002-2021, 9999 = Unknown

Intermittent Claudication First Examiner Opinion

Intermittent claudication	0 = No 1 = Yes 2 = Maybe 9 = Unknown
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Additional Comments

Venous and Peripheral Arterial Disease and Intermittent Claudication Opinion

Since you last provided medical information **Desde la última vez que nos dió información médica. . .**

Did you have any of the following cardiovascular procedures? (if procedure was repeated, code only FIRST and provide narrative) ¿Ha tenido alguno de los siguientes procedimientos cardiovasculares?		
Heart valvular surgery Cirugía de válvula del corazón		0 = No 1 = Yes 2 = Maybe 9 = Unknown
If "Yes" or "Maybe"		
YEAR - Heart valvular surgery	¿En qué año tuvo esta cirugía?	2002 – 2021; 9999 = Unknown
Exercise stress test or other type of cardiac stress test Examen de estrés por ejercicio u otro tipo de examen de estrés del corazón		0 = No 1 = Yes 2 = Maybe 9 = Unknown
If "Yes" or "Maybe"		
YEAR - Exercise stress test	¿En qué año?	2002 – 2021; 9999 = Unknown
Coronary arteriogram Arteriograma coronario		0 = No 1 = Yes 2 = Maybe 9 = Unknown
If "Yes" or "Maybe"		
YEAR - Coronary artery angioplasty or stent	¿En qué año?	2002 – 2021; 9999 = Unknown
Coronary artery angioplasty or stent Angioplastia de la arteria coronaria o stent		0 = No 1 = Yes 2 = Maybe 9 = Unknown
If "Yes" or "Maybe"		
YEAR - Coronary artery angioplasty or stent	¿En qué año?	2002 – 2021; 9999 = Unknown
Coronary bypass surgery Baypass coronario		0 = No 1 = Yes 2 = Maybe 9 = Unknown
If "Yes" or "Maybe"		
YEAR - Coronary bypass surgery	¿En qué año?	2002 – 2021; 9999 = Unknown
Permanent pacemaker insertion Inserción de marcapasos		0 = No 1 = Yes 2 = Maybe 9 = Unknown
If "Yes" or "Maybe"		
YEAR - Permanent pacemaker insertion	¿En qué año?	2002 – 2021; 9999 = Unknown
Carotid artery surgery or stent Cirugía de la arteria carótida o stent		0 = No 1 = Yes 2 = Maybe 9 = Unknown
If "Yes" or "Maybe"		
YEAR - Carotid artery surgery or stent	¿En qué año?	2002 – 2021; 9999 = Unknown

Thoracic aorta surgery Cirugía de la aorta torácica		0 = No 1 = Yes 2 = Maybe 9 = Unknown
If "Yes" or "Maybe"		
YEAR - Thoracic aorta surgery	¿En qué año?	2002 – 2021; 9999 = Unknown
Abdominal aorta surgery Cirugía de la aorta abdominal		0 = No 1 = Yes 2 = Maybe 9 = Unknown
If "Yes" or "Maybe"		
YEAR - Abdominal aorta surgery	¿En qué año?	2002 – 2021; 9999 = Unknown
Femoral or lower extremity surgery Cirugía del femoral o pierna		0 = No 1 = Yes 2 = Maybe 9 = Unknown
If "Yes" or "Maybe"		
YEAR - Femoral or lower extremity surgery	¿En qué año?	2002 – 2021; 9999 = Unknown
Lower extremity amputation Amputación de la pierna		0 = No 1 = Yes 2 = Maybe 9 = Unknown
If "Yes" or "Maybe"		
YEAR - Lower extremity amputation	¿En qué año?	2002 – 2021; 9999 = Unknown
Other cardiovascular procedure Otro procedimiento cardiovascular (specify below)		0 = No 1 = Yes 2 = Maybe 9 = Unknown
If "Yes" or "Maybe"		
YEAR - Other cardiovascular procedure	¿En qué año?	2002 – 2021; 9999 = Unknown
	Specify other cardiovascular procedure	¿Qué procedimiento?
Write in other procedures, year done, location if more than one.		Character field

Additional Comments

CVD Procedures

Le voy a tomar la presión arterial...

BP cuff size	0 = Pediatric 1 = Regular adult 2 = Large adult 3 = Thigh 9 = Unknown
Protocol modification	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
Comments for protocol modification	Character field
Systolic (to nearest 2 mmHg)	999 = Unknown
Diastolic (to nearest 2 mmHg)	999 = Unknown

Additional CommentsBlood Pressure 2nd MD Reading

Since your last provided medical information have you had a cancer or tumor? Desde la última vez que nos dió información médica ¿ha tenido cáncer o algún tumor?		0 = No 1 = Yes 2 = Maybe 9 = Unknown
If "Yes" or "Maybe"		
Cancer or tumor Cáncer o tumor		15 = Bladder Vejiga 17 = Brain Cerebro 11 = Breast Seno 12 = Cervix / Uterus Cervix/Utero 3 = Colon / Rectum Colon/Recto 1 = Esophagus Esófago 16 = Kidney Riñón 7 = Larynx Laringe 9 = Leukemia Leucemia 18 = Lymphoma Linfoma 13 = Ovary Ovario 6 = Pancreas Páncreas 14 = Prostate Próstata 10 = Skin Piel 2 = Stomach Estómago 4 = Thyroid Tiroides 8 = Trachea/Bronchus/Lung Tráquea/Bronquios/Pulmón
Cancer or tumor site for "Other"		Character field
Diagnosis Diagnosis		1 = Cancer 2 = Maybe cancer 3 = Benign
Have medical encounter details been entered on M01 Medical Encounters? ¿Me dió los detalles de ésta visita al doctor al principio?		0 = No; 1 = Yes
If "No"		
Year first diagnosed ¿En qué año en que lo diagnosticaron primero?		2002-2021 9999 = Unknown
DATE details Qué fecha? (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)		Character field
Name of MD Nombre del doctor		Character field
Location of MD ¿Dónde se localiza el doctor?		Character field
Was a diagnostic biopsy done at a different location? ¿Le hicieron la biopsia en un lugar distinto?		0 = No; 1 = Yes
If "Yes"		
Year of biopsy Año en que le hicieron la biopsia		2002-2021 9999 = Unknown
DATE details Qué fecha? (e.g. 10/2, April, Summer, August-Nov., Unknown etc.)		Character field
Name of MD for biopsy ¿Quién le hizo la biopsia?		Character field
Location of biopsy ¿Dónde le hicieron la biopsia?		Character field

Have you had a second cancer or tumor?

¿Ha tenido cancer o algún tumor por segunda vez?

¿Ha tenido un tercer cancer o tumor?

¿Ha tenido un cuarto cancer o tumor?

¿Ha tenido un quinto cancer o tumor?

¿Ha tenido un sexto cancer o tumor?

0 = No

1 = Yes

2 = Maybe

9 = Unknown

Block of questions ("Cancer or tumor" to "Have you had a second cancer or tumor") **Repeats 4 more times**

Additional Comments

Cancer

Heart Diagnoses ¿Ha tenido problemas cardiacos diagnosticados? Como...

One choice per line	0 = No	1 = Yes	2 = Maybe	9 = Unknown
Aortic valve disease Problemas con la válvula aórtica	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mitral valve disease Problemas con la válvula mitral	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Neurological Disease ¿Problemas neurológicos o del cerebro diagnosticados? Como...

One choice per line	0 = No	1 = Yes	2 = Maybe	9 = Unknown
Dementia Demencia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Parkinson's Disease Parkinsons	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Adult seizure disorder Convulsiones	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Migraine Migrañas	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other neurological disease Otros problemas neurológicos	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If "Other neurological disease" = "Yes" or "Maybe"				
Specify other neurological disease			Character field	
Additional comments for neurological disease			Character field	

Endocrine ¿Problemas de hormonas o de metabolismo diagnosticados? Como...

One choice per line	0 = No	1 = Yes	2 = Maybe	9 = Unknown
Thyroid disease Problemas de tiroides	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Diabetes Mellitus Diabetes Mellitus	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other endocrine disorders ¿Otros problemas endocrinológicos?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If "Other endocrine disorders" = "Yes" or "Maybe"				
Specify other endocrine disorders			Character field	

GU/GYN ¿Problemas de riñones o genitales?

One choice per line	0 = No	1 = Yes	2 = Maybe	9 = Unknown
Renal disease Problemas con los riñones	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If "Yes" or "Maybe"				
Specify renal disease ¿Qué problema?			Character field	
If "Male"				
One choice per line	0 = No	1 = Yes	2 = Maybe	9 = Unknown
Prostate disease Problemas con la próstata	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If "Female"				
One choice per line	0 = No	1 = Yes	2 = Maybe	9 = Unknown
Gynecological problems Problemas ginecológicos	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If "Yes" or "Maybe"				
Specify gynecological problems ¿Qué problemas?				Character field

Pulmonary **¿Problemas pulmonares diagnosticados? Como...**

One choice per line	0 = No	1 = Yes	2 = Maybe	9 = Unknown
Emphysema Enfisema	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pneumonia Pulmonía	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Asthma Asma	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Obstructive sleep apnea Apnea del sueño obstructiva	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other pulmonary disease Otro problema pulmonar	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If "Other pulmonary disease" = "Yes" or "Maybe"				
Specify other pulmonary disease				Character field

Rheumatologic Disorders **¿Problemas reumatológicos o de inflamación? Como...**

One choice per line	0 = No	1 = Yes	2 = Maybe	9 = Unknown
Gout Gota	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Degenerative joint disease Degeneración de las coyunturas o articulaciones	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Rheumatoid arthritis Artritis reumatoide	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other muscular or connective tissue disease Otros problemas musculares o del tejido conectivo	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If "Other muscular or connective tissue disease" = "Yes" or "Maybe"				
Specify other muscular or connective tissue disease				Character field

GI **¿Problemas gastrointestinales diagnosticados? Como...**

One choice per line	0 = No	1 = Yes	2 = Maybe	9 = Unknown
Gallbladder disease Vesícula	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
GERD/ ulcer disease Úlceras en el estómago	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Liver disease Problemas del hígado	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other GI disease Otros problemas del tracto digestivo	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If "Other GI disease" = "Yes" or "Maybe"				
Specify other GI disease ¿Qué problemas?				Character field

Blood ¿Problemas de la sangre?

One choice per line	0 = No	1 = Yes	2 = Maybe	9 = Unknown
Hematologic disorder Problemas hematológicos	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bleeding disorder Problemas de sangrado	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Infectious Disease ¿Enfermedades infecciosas?

One choice per line	0 = No	1 = Yes	2 = Maybe	9 = Unknown
Infectious disease	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If "Yes" or "Maybe"				
Specify infectious disease ¿Qué infección?			Character field	

Mental Health ¿Problemas de salud mental diagnosticados? Como...

One choice per line	0 = No	1 = Yes	2 = Maybe	9 = Unknown
Depression Depresión	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Anxiety Ansiedad	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other mental health condition Otras condiciones mentales	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If "Other mental health condition" = "Yes" or "Maybe"				
Specify other mental health condition ¿Qué condición?			Character field	

Other ¿Algún otro problema diagnosticado? Como problemas con...

One choice per line	0 = No	1 = Yes	2 = Maybe	9 = Unknown
Eye Ojos	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ear, nose and throat (ENT) Oído, Naríz y Garganta	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Skin Piel	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other Eye, ENT or Skin ¿Alguna otra cosa con los ojos, oídos, nariz, garganta o piel?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If "Other Eye, ENT or Skin" = "Yes" or "Maybe"				
Specify other Eye, ENT or Skin ¿Qué problemas?			Character field	

Additional Comments

Clinical Diagnostic Impression

Form is intentionally left blank <input type="checkbox"/> checked = "Yes"	Check box
Reason why form was left blank _____	Character field
Technician Number _____ Select from drop down	Character field

If form was intentionally left blank none of the following questions would be asked.

Basic Information

<p>What state do you reside in? ¿En qué estado vive?</p> <p>If resides outside the USA, code ZZ. If plans to wear accelerometer while visiting USA, code state of visit.</p>	<p>AL = AL = Alabama AK = AK = Alaska AZ = AZ = Arizona AR = AR = Arkansas CA = CA = California CO = CO = Colorado CT = CT = Connecticut DC = DC = Washington DC DE = DE = Delaware FL = FL = Florida GA = GA = Georgia HI = HI = Hawaii ID = ID = Idaho IL = IL = Illinois IN = IN = Indiana IA = IA = Iowa KS = KS = Kansas KY = KY = Kentucky LA = LA = Louisiana ME = ME = Maine MD = MD = Maryland MA = MA = Massachusetts MI = MI = Michigan MN = MN = Minnesota MS = MS = Mississippi MO = MO = Missouri MT = MT = Montana NE = NE = Nebraska NV = NV = Nevada NH = NH = New Hampshire NJ = NJ = New Jersey NM = NM = New Mexico NY = NY = New York NC = NC = North Carolina ND = ND = North Dakota OH = OH = Ohio OK = OK = Oklahoma OR = OR = Oregon PA = PA = Pennsylvania RI = RI = Rhode Island SC = SC = South Carolina SD = SD = South Dakota TN = TN = Tennessee TX = TX = Texas UT = UT = Utah VT = VT = Vermont VA = VA = Virginia WA = WA = Washington WV = WV = West Virginia WI = WI = Wisconsin WY = WY = Wyoming ZZ = ZZ = Outside United States</p>
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Anthropometry

Le voy a tomar el...

Weight	Peso	_ _ _	To the nearest pound 400 = 400 or more 888 = Refused 999 = Not done or Unknown
Protocol modification - Weight		_	1 = Yes
If "Yes"			
Comments protocol modification – Weight _____		Character field	
Height	Altura	_ _ _	Inches, to next lower 1/4 inch 88.88 = Refused 99.99 = Not done or Unknown
Protocol modification - Height		_	1 = Yes
If "Yes"			
Comments protocol modification – Height _____		Character field	
Waist girth at umbilicus	Medida de la cintura	_ _	Inches, to next lower 1/4 inch 88.88 = Refused 99.99 = Not done or Unknown
Protocol modification - Waist girth		_	1 = Yes
If "Yes"			
Comments protocol modification – Waist girth _____		Character field	
Hip girth	Medida de la cadera	_ _	Inches, to next lower 1/4 inch 88.88 = Refused 99.99 = Not done or Unknown
Protocol modification - Hip girth		_	1 = Yes
If "Yes"			
Comments protocol modification – Hip girth _____		Character field	

Additional Comments

Hand Grip Test

Prueba de la Fuerza en las Manos

Cuando le diga “ahora” apriete tan fuerte como pueda hasta que le diga “ya”

Van a ser tres veces de cada lado. Listo? “Ahora” ... (apriete, apriete) ... “Ya”

Form is intentionally left blank <input type="checkbox"/> checked = “Yes”	Check box
Reason why form was left blank _____	Character field
Technician Number _____ Select from drop down	Character field

If form was intentionally left blank none of the following questions would be asked.

Right Hand Mano Derecha	
Trial 1	<input type="text"/> <input type="text"/> <input type="text"/> Nearest kilogram 99 = Unknown
Trial 2	<input type="text"/> <input type="text"/> <input type="text"/> Nearest kilogram 99 = Unknown
Trial 3	<input type="text"/> <input type="text"/> <input type="text"/> Nearest kilogram 99 = Unknown
Left Hand Mano Izquierda	
Trial 1	<input type="text"/> <input type="text"/> <input type="text"/> Nearest kilogram 99 = Unknown
Trial 2	<input type="text"/> <input type="text"/> <input type="text"/> Nearest kilogram 99 = Unknown
Trial 3	<input type="text"/> <input type="text"/> <input type="text"/> Nearest kilogram 99 = Unknown
Check only if HAND GRIP test was NOT completed or NOT attempted? <input type="checkbox"/>	1 = Test NOT completed or NOT attempted
If checked	
If "Test NOT completed or NOT attempted" why not? <input type="checkbox"/>	1 = Physical limitation 2 = Refused 3 = Other 9 = Unknown
Other reason test not done _____	Character field

Additional Comments

Hand Grip Test

Form is intentionally left blank	Check box
Reason why form was left blank	Character field
Technician Number	Character field

If form was intentionally left blank none of the following questions would be asked.

The next questions ask about your feelings. **Las siguientes preguntas son acerca de cómo se ha sentido**

For each statement, please say how often you felt that way DURING THE PAST WEEK

Para cada declaración, por favor diga cuántas veces se sintió así DURANTE LA ULTIMA SEMANA

<p>During the past week, I was bothered by things that don't usually bother me.</p> <p>Durante la última semana me molesté por cosas que generalmente no me molestan</p>	<p>0 = Rarely or none of the time (less than 1 day) Raramente o casi nada del tiempo (menos de 1 día)</p> <p>1 = Some or a little of the time (1-2 days) Algo o un poco del tiempo (1 a 2 días)</p> <p>2 = Occasionally or a moderate amount of the time (3-4 days) Ocasionalmente o una moderada parte del tiempo (3 a 4 días)</p> <p>3 = Most or all of the time (5-7 days) La mayoría del tiempo (5 a 7 días)</p>
<p>I did not feel like eating; my appetite was poor.</p> <p>No me dieron ganas de comer. No tuve apetito</p>	<p>0 = Rarely or none of the time (less than 1 day) Raramente o casi nada del tiempo (menos de 1 día)</p> <p>1 = Some or a little of the time (1-2 days) Algo o un poco del tiempo (1 a 2 días)</p> <p>2 = Occasionally or a moderate amount of the time (3-4 days) Ocasionalmente o una moderada parte del tiempo (3 a 4 días)</p> <p>3 = Most or all of the time (5-7 days) La mayoría del tiempo (5 a 7 días)</p>
<p>I felt that I could not shake off the blues even with the help of my family or friends.</p> <p>Sentí que no se me quitaba la depresión ni con ayuda de mi familia y amigos</p>	<p>0 = Rarely or none of the time (less than 1 day) Raramente o casi nada del tiempo (menos de 1 día)</p> <p>1 = Some or a little of the time (1-2 days) Algo o un poco del tiempo (1 a 2 días)</p> <p>2 = Occasionally or a moderate amount of the time (3-4 days) Ocasionalmente o una moderada parte del tiempo (3 a 4 días)</p> <p>3 = Most or all of the time (5-7 days) La mayoría del tiempo (5 a 7 días)</p>
<p>I felt that I was just as good as other people.</p> <p>Me sentí tan bien como los demás</p>	<p>0 = Rarely or none of the time (less than 1 day) Raramente o casi nada del tiempo (menos de 1 día)</p> <p>1 = Some or a little of the time (1-2 days) Algo o un poco del tiempo (1 a 2 días)</p> <p>2 = Occasionally or a moderate amount of the time (3-4 days) Ocasionalmente o una moderada parte del tiempo (3 a 4 días)</p> <p>3 = Most or all of the time (5-7 days) La mayoría del tiempo (5 a 7 días)</p>
<p>I had trouble keeping my mind on what I was doing.</p> <p>Me costó trabajo concentrarme en lo que estaba haciendo</p>	<p>0 = Rarely or none of the time (less than 1 day) Raramente o casi nada del tiempo (menos de 1 día)</p> <p>1 = Some or a little of the time (1-2 days) Algo o un poco del tiempo (1 a 2 días)</p> <p>2 = Occasionally or a moderate amount of the time (3-4 days) Ocasionalmente o una moderada parte del tiempo (3 a 4 días)</p> <p>3 = Most or all of the time (5-7 days) La mayoría del tiempo (5 a 7 días)</p>

<p>During the past week, I felt depressed.</p> <p>Durante la última semana me sentí deprimido (deprimida)</p>	<p>0 = Rarely or none of the time (less than 1 day) Raramente o casi nada del tiempo (menos de 1 día)</p> <p>1 = Some or a little of the time (1-2 days) Algo o un poco del tiempo (1 a 2 días)</p> <p>2 = Occasionally or a moderate amount of the time (3-4 days) Ocasionalmente o una moderada parte del tiempo (3 a 4 días)</p> <p>3 = Most or all of the time (5-7 days) La mayoría del tiempo (5 a 7 días)</p>
<p>I felt everything I did was an effort.</p> <p>Sentí que todo lo que hice me costó mucho trabajo</p>	<p>0 = Rarely or none of the time (less than 1 day) Raramente o casi nada del tiempo (menos de 1 día)</p> <p>1 = Some or a little of the time (1-2 days) Algo o un poco del tiempo (1 a 2 días)</p> <p>2 = Occasionally or a moderate amount of the time (3-4 days) Ocasionalmente o una moderada parte del tiempo (3 a 4 días)</p> <p>3 = Most or all of the time (5-7 days) La mayoría del tiempo (5 a 7 días)</p>
<p>I felt hopeful about the future.</p> <p>Me sentí con esperanzas sobre el futuro</p>	<p>0 = Rarely or none of the time (less than 1 day) Raramente o casi nada del tiempo (menos de 1 día)</p> <p>1 = Some or a little of the time (1-2 days) Algo o un poco del tiempo (1 a 2 días)</p> <p>2 = Occasionally or a moderate amount of the time (3-4 days) Ocasionalmente o una moderada parte del tiempo (3 a 4 días)</p> <p>3 = Most or all of the time (5-7 days) La mayoría del tiempo (5 a 7 días)</p>
<p>I thought my life had been a failure.</p> <p>Pensé que mi vida ha sido un fracaso</p>	<p>0 = Rarely or none of the time (less than 1 day) Raramente o casi nada del tiempo (menos de 1 día)</p> <p>1 = Some or a little of the time (1-2 days) Algo o un poco del tiempo (1 a 2 días)</p> <p>2 = Occasionally or a moderate amount of the time (3-4 days) Ocasionalmente o una moderada parte del tiempo (3 a 4 días)</p> <p>3 = Most or all of the time (5-7 days) La mayoría del tiempo (5 a 7 días)</p>
<p>I felt fearful.</p> <p>Me sentí con miedo</p>	<p>0 = Rarely or none of the time (less than 1 day) Raramente o casi nada del tiempo (menos de 1 día)</p> <p>1 = Some or a little of the time (1-2 days) Algo o un poco del tiempo (1 a 2 días)</p> <p>2 = Occasionally or a moderate amount of the time (3-4 days) Ocasionalmente o una moderada parte del tiempo (3 a 4 días)</p> <p>3 = Most or all of the time (5-7 days) La mayoría del tiempo (5 a 7 días)</p>
<p>During the past week, my sleep was restless.</p> <p>Durante la semana pasada no dormí bien por la noche</p>	<p>0 = Rarely or none of the time (less than 1 day) Raramente o casi nada del tiempo (menos de 1 día)</p> <p>1 = Some or a little of the time (1-2 days) Algo o un poco del tiempo (1 a 2 días)</p> <p>2 = Occasionally or a moderate amount of the time (3-4 days) Ocasionalmente o una moderada parte del tiempo (3 a 4 días)</p> <p>3 = Most or all of the time (5-7 days) La mayoría del tiempo (5 a 7 días)</p>
<p>I was happy.</p> <p>Me sentí feliz</p>	<p>0 = Rarely or none of the time (less than 1 day) Raramente o casi nada del tiempo (menos de 1 día)</p> <p>1 = Some or a little of the time (1-2 days) Algo o un poco del tiempo (1 a 2 días)</p> <p>2 = Occasionally or a moderate amount of the time (3-4 days) Ocasionalmente o una moderada parte del tiempo (3 a 4 días)</p> <p>3 = Most or all of the time (5-7 days) La mayoría del tiempo (5 a 7 días)</p>

<p>I talked less than usual. Hablé menos de lo usual</p>	<p>0 = Rarely or none of the time (less than 1 day) Raramente o casi nada del tiempo (menos de 1 día)</p> <p>1 = Some or a little of the time (1-2 days) Algo o un poco del tiempo (1 a 2 días)</p> <p>2 = Occasionally or a moderate amount of the time (3-4 days) Ocasionalmente o una moderada parte del tiempo (3 a 4 días)</p> <p>3 = Most or all of the time (5-7 days) La mayoría del tiempo (5 a 7 días)</p>
<p>I felt lonely. Me sentí solo (sola)</p>	<p>0 = Rarely or none of the time (less than 1 day) Raramente o casi nada del tiempo (menos de 1 día)</p> <p>1 = Some or a little of the time (1-2 days) Algo o un poco del tiempo (1 a 2 días)</p> <p>2 = Occasionally or a moderate amount of the time (3-4 days) Ocasionalmente o una moderada parte del tiempo (3 a 4 días)</p> <p>3 = Most or all of the time (5-7 days) La mayoría del tiempo (5 a 7 días)</p>
<p>People were unfriendly. La gente no fué amigable conmigo</p>	<p>0 = Rarely or none of the time (less than 1 day) Raramente o casi nada del tiempo (menos de 1 día)</p> <p>1 = Some or a little of the time (1-2 days) Algo o un poco del tiempo (1 a 2 días)</p> <p>2 = Occasionally or a moderate amount of the time (3-4 days) Ocasionalmente o una moderada parte del tiempo (3 a 4 días)</p> <p>3 = Most or all of the time (5-7 days) La mayoría del tiempo (5 a 7 días)</p>
<p>I enjoyed life. Disfruté de la vida</p>	<p>0 = Rarely or none of the time (less than 1 day) Raramente o casi nada del tiempo (menos de 1 día)</p> <p>1 = Some or a little of the time (1-2 days) Algo o un poco del tiempo (1 a 2 días)</p> <p>2 = Occasionally or a moderate amount of the time (3-4 days) Ocasionalmente o una moderada parte del tiempo (3 a 4 días)</p> <p>3 = Most or all of the time (5-7 days) La mayoría del tiempo (5 a 7 días)</p>
<p>I had crying spells. Me dió por llorar</p>	<p>0 = Rarely or none of the time (less than 1 day) Raramente o casi nada del tiempo (menos de 1 día)</p> <p>1 = Some or a little of the time (1-2 days) Algo o un poco del tiempo (1 a 2 días)</p> <p>2 = Occasionally or a moderate amount of the time (3-4 days) Ocasionalmente o una moderada parte del tiempo (3 a 4 días)</p> <p>3 = Most or all of the time (5-7 days) La mayoría del tiempo (5 a 7 días)</p>
<p>I felt sad. Me sentí triste</p>	<p>0 = Rarely or none of the time (less than 1 day) Raramente o casi nada del tiempo (menos de 1 día)</p> <p>1 = Some or a little of the time (1-2 days) Algo o un poco del tiempo (1 a 2 días)</p> <p>2 = Occasionally or a moderate amount of the time (3-4 days) Ocasionalmente o una moderada parte del tiempo (3 a 4 días)</p> <p>3 = Most or all of the time (5-7 days) La mayoría del tiempo (5 a 7 días)</p>

<p>I felt that people disliked me.</p> <p>Sentí que no le gusto a la gente</p>	<p>0 = Rarely or none of the time (less than 1 day) Raramente o casi nada del tiempo (menos de 1 día)</p> <p>1 = Some or a little of the time (1-2 days) Algo o un poco del tiempo (1 a 2 días)</p> <p>2 = Occasionally or a moderate amount of the time (3-4 days) Ocasionalmente o una moderada parte del tiempo (3 a 4 días)</p> <p>3 = Most or all of the time (5-7 days) La mayoría del tiempo (5 a 7 días)</p>
<p>I could not "get going".</p> <p>No podía "empezar" mi día</p>	<p>0 = Rarely or none of the time (less than 1 day) Raramente o casi nada del tiempo (menos de 1 día)</p> <p>1 = Some or a little of the time (1-2 days) Algo o un poco del tiempo (1 a 2 días)</p> <p>2 = Occasionally or a moderate amount of the time (3-4 days) Ocasionalmente o una moderada parte del tiempo (3 a 4 días)</p> <p>3 = Most or all of the time (5-7 days) La mayoría del tiempo (5 a 7 días)</p>

Additional Comments

CES-D

Form is intentionally left blank	Check box
Reason why form was left blank	Character field
Technician Number	Character field

If form was intentionally left blank none of the following questions would be asked.

One choice per line	0 = No	1 = Yes	9 = Unknown Desconocido
Are you able to do heavy work around the house, like shoveling snow or washing windows, walls, or floors without help? ¿Puede hacer trabajo pesado de casa, como quitar nieve, lavar ventanas, paredes o pisos sin ayuda?	_	_	_
Are you able to walk half a mile without help? (About 4-6 blocks) ¿Puede caminar media milla sin ayuda? (como 4 o 6 cuadras)	_	_	_
Are you able to walk up and down one flight of stairs without help? ¿Puede subir y bajar un piso de escaleras sin ayuda?	_	_	_

Additional Comments

Rosow-Breslau

Physical Activity Index (PAI)

Índice (PAI) de Actividad Física

Form is intentionally left blank	Check box
Reason why form was left blank	Character field
Technician Number	Character field

If form was intentionally left blank none of the following questions would be asked.

Rest and Activity for a TYPICAL DAY over the PAST YEAR.

Descanso y Actividad en un Día Típico durante el Año Pasado

A typical day = most days of the week

Un día típico = la mayoría de los días de la semana

<p>SLEEP: Number of hours that you typically sleep? ¿Cuántas horas duerme normalmente?</p>	99 = Unknown Desconocido
<p>SEDENTARY: Number of hours typically sitting? ¿Cuántas horas permanece sentado en un día normal?</p>	99 = Unknown Desconocido
<p>SLIGHT ACTIVITY: Number of hours with activities such as standing, walking? En un día típico ¿cuántas horas está de pie o caminando?</p>	99 = Unknown Desconocido
<p>MODERATE ACTIVITY: Number of hours with activities such as housework (vacuum, dust, yard chores, climbing stairs, light sports such as bowling, golf)? En un día típico ¿cuántas horas hace trabajo de casa como pasar la aspiradora, limpiar, hacer el jardín, subir escaleras, o hace deportes ligeros como boliche o golf?</p>	99 = Unknown Desconocido
<p>HEAVY ACTIVITY: Number of hours with activities such as heavy household work, heavy yard work such as stacking or chopping wood, exercise such as intensive sports, jogging, swimming etc.? En un día normal ¿cuántas horas hace actividades de casa pesado, o trabajo de jardinería pesado, corta leña o hace ejercicio intenso como nadar o hacer jogging?</p>	99 = Unknown Desconocido
Rest and Activity Hours - TOTAL:	Calculated value

Additional Comments

Form is intentionally left blank	Check box
Reason why form was left blank	Character field
Technician Number	Character field

If form was intentionally left blank none of the following questions would be asked.

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

Ahora le voy a preguntar sobre sus actividades físicas. Solo incluya el tiempo en que realmente hizo la actividad. Por ejemplo, estar sentado junto a la alberca no cuenta como tiempo de estar nadando. Tiempo en la silla de esquiar no cuenta como estar esquiando.

First I'll ask about **VIGOROUS ACTIVITIES**. Vigorous activities increase your heart rate, or make you sweat doing them, or make you 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.

Primero le voy a preguntar sobre ACTIVIDADES VIGOROSAS. Estas incrementan su ritmo cardiaco o lo hacen sudar, o respirar más fuerte o incrementan su temperatura. Si hace una actividad pero no vigorosamente, por favor inclúyala después cuando le pregunte sobre actividades no vigorosas.

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.

En los últimos 12 meses, hizo por lo menos una hora en total al mes, una de las siguientes actividades? Por ejemplo, pudo haber hecho 3 sesiones de 20 minutos durante el mes.

In the past 12 months for at least one hour total time in any month did you do En los últimos 12 meses, hizo por lo menos durante una hora en cualquier mes....	0 = No; 1 = Yes; 9 = Unknown
Vigorous jogging or running? ¿Corrió o hizo jogging vigorosamente?	
If "Yes"	
How many months did you do this activity? ¿Cuántos meses hizo esta actividad?	99 = Unknown
How many times per month did you do this activity? ¿Cuántas veces en el mes hizo esta actividad?	99 = Unknown
How long did you do this activity on average each time? En promedio ¿por cuánto tiempo hizo esta actividad cada vez?	Number of minutes 999 = Unknown
In the past 12 months for at least one hour total time in any month did you do En los últimos 12 meses, hizo por lo menos durante una hora en cualquier mes....	0 = No; 1 = Yes; 9 = Unknown
Vigorous racket sports? ¿Deportes de raqueta vigorosamente?	
If "Yes"	
How many months did you do this activity? ¿Cuántos meses hizo esta actividad?	99 = Unknown
How many times per month did you do this activity? ¿Cuántas veces en el mes hizo esta actividad?	99 = Unknown

How long did you do this activity on average each time? En promedio ¿por cuánto tiempo hizo esta actividad cada vez?	Number of minutes 999 = Unknown
In the past 12 months for at least one hour total time in any month did you do En los últimos 12 meses, hizo por lo menos durante una hora en cualquier mes.... Bicycle faster than 10 miles/hour or exercise hard on an exercise bicycle, elliptical, stair-master, treadmill, etc. Bicicleta a más de 10 millas por hora o ejercicio duro en bicicleta estacionaria, elíptica, stair-master, treadmill, etc?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
How many months did you do this activity? ¿Cuántos meses hizo esta actividad?	99 = Unknown
How many times per month did you do this activity? ¿Cuántas veces en el mes hizo esta actividad?	99 = Unknown
How long did you do this activity on average each time? En promedio ¿por cuánto tiempo hizo esta actividad cada vez?	Number of minutes 999 = Unknown
In the past 12 months for at least one hour total time in any month did you do En los últimos 12 meses, hizo por lo menos durante una hora en cualquier mes.... Vigorous swimming? Nadó vigorosamente?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
How many months did you do this activity? ¿Cuántos meses hizo esta actividad?	99 = Unknown
How many times per month did you do this activity? ¿Cuántas veces en el mes hizo esta actividad?	99 = Unknown
How long did you do this activity on average each time? En promedio ¿por cuánto tiempo hizo esta actividad cada vez?	Number of minutes 999 = Unknown
In the past 12 months for at least one hour total time in any month did you do En los últimos 12 meses, hizo por lo menos durante una hora en cualquier mes.... Vigorous exercise class or vigorous dancing? Clase vigorosa de ejercicio o bailó vigorosamente?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
How many months did you do this activity? ¿Cuántos meses hizo esta actividad?	99 = Unknown
How many times per month did you do this activity? ¿Cuántas veces en el mes hizo esta actividad?	99 = Unknown
How long did you do this activity on average each time? En promedio ¿por cuánto tiempo hizo esta actividad cada vez?	Number of minutes 999 = Unknown
In the past 12 months for at least one hour total time in any month did you do En los últimos 12 meses, hizo por lo menos durante una hora en cualquier mes.... Any vigorous job activities such as lifting, carrying, or digging? Algún trabajo vigoroso como levantar, cargar o excavar?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
How many months did you do this activity? ¿Cuántos meses hizo esta actividad?	99 = Unknown

How many times per month did you do this activity? ¿Cuántas veces en el mes hizo esta actividad?	99 = Unknown
How long did you do this activity on average each time? En promedio ¿por cuánto tiempo hizo esta actividad cada vez?	Number of minutes 999 = Unknown
In the past 12 months for at least one hour total time in any month did you do En los últimos 12 meses, hizo por lo menos durante una hora en cualquier mes.... Any home activities such as snow shoveling, moving heavy objects, or weight lifting (including weight training)? Actividades de casa como palear nieve, mover objetos pesados o levantar pesas (incluyendo por ejercicio)	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
How many months did you do this activity? ¿Cuántos meses hizo esta actividad?	99 = Unknown
How many times per month did you do this activity? ¿Cuántas veces en el mes hizo esta actividad?	99 = Unknown
How long did you do this activity on average each time? En promedio ¿por cuánto tiempo hizo esta actividad cada vez?	Number of minutes 999 = Unknown
In the past 12 months for at least one hour total time in any month did you do En los últimos 12 meses, hizo por lo menos durante una hora en cualquier mes.... Other strenuous sports such as basketball, football, skating, skiing, soccer, etc.? <input type="checkbox"/> Otros deportes exhaustivos como basketball, football Americano o soccer, patinar, esquiar, etc?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
How many months did you do this activity? ¿Cuántos meses hizo esta actividad?	99 = Unknown
How many times per month did you do this activity? ¿Cuántas veces en el mes hizo esta actividad?	99 = Unknown
How long did you do this activity on average each time? En promedio ¿por cuánto tiempo hizo esta actividad cada vez?	Number of minutes 999 = Unknown

Additional Comments

Form is intentionally left blank <input type="checkbox"/> checked = "Yes"	Check box
Reason why form was left blank _____	Character field
Technician Number _____ Select from drop down	Character field

If form was intentionally left blank none of the following questions would be asked.

Leisure Activities **Actividades por placer**

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...

Ahora me gustaría preguntarle sobre actividades que hace POR GUSTO. De las actividades que le voy a decir, dígame si las ha hecho en los últimos 12 meses por lo menos durante una hora en total, en cualquier mes...

In the past 12 months for at least one hour total time in any month did you... En los últimos 12 meses, hizo por lo menos durante una hora en cualquier mes....	
Do non-strenuous sports such as softball, shooting baskets, volleyball, ping pong, or leisurely jogging, swimming or biking, which we haven't included above? ¿Deportes no extenuantes como softball, tiro de canasta, volleyball, ping pong, o hacer jogging, nadir o andar en bicicleta que no lo hayamos incluido arriba?	0 = No; 1 = Yes; 9 = Unknown

If "Yes"	
How many months did you do this activity? ¿Cuántos meses hizo esta actividad?	99 = Unknown
How many times per month did you do this activity? ¿Cuántas veces en el mes hizo esta actividad?	99 = Unknown
How long did you do this activity on average each time? En promedio ¿por cuánto tiempo hizo esta actividad cada vez?	Number of minutes 999 = Unknown

In the past 12 months for at least one hour total time in any month did you do En los últimos 12 meses, hizo por lo menos durante una hora en cualquier mes....	
Take walks or hikes or walk to work? ¿Tomar paseos o caminatas o ir a pie al trabajo?	0 = No; 1 = Yes; 9 = Unknown

If "Yes"	
How many months did you do this activity? ¿Cuántos meses hizo esta actividad?	99 = Unknown
How many times per month did you do this activity? ¿Cuántas veces en el mes hizo esta actividad?	99 = Unknown
How long did you do this activity on average each time? En promedio ¿por cuánto tiempo hizo esta actividad cada vez?	Number of minutes 999 = Unknown

In the past 12 months for at least one hour total time in any month did you do En los últimos 12 meses, hizo por lo menos durante una hora en cualquier mes....	
Bowl or play golf? ¿Jugar boliche o golf?	0 = No; 1 = Yes; 9 = Unknown

If "Yes"	
How many months did you do this activity? ¿Cuántos meses hizo esta actividad?	99 = Unknown

How many times per month did you do this activity? ¿Cuántas veces en el mes hizo esta actividad?	99 = Unknown
How long did you do this activity on average each time? En promedio ¿por cuánto tiempo hizo esta actividad cada vez?	Number of minutes 999 = Unknown
In the past 12 months for at least one hour total time in any month did you do En los últimos 12 meses, hizo por lo menos durante una hora en cualquier mes....	
Do home exercise or calisthenics? ¿Hacer ejercicio en casa o calistenicos?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
How many months did you do this activity? ¿Cuántos meses hizo esta actividad?	99 = Unknown
How many times per month did you do this activity? ¿Cuántas veces en el mes hizo esta actividad?	99 = Unknown
How long did you do this activity on average each time? En promedio ¿por cuánto tiempo hizo esta actividad cada vez?	Number of minutes 999 = Unknown
In the past 12 months for at least one hour total time in any month did you do En los últimos 12 meses, hizo por lo menos durante una hora en cualquier mes....	
Do home maintenance or gardening, including carpentry, painting, raking, mowing, etc.? ¿Mantenimiento del jardín, incluyendo carpintería, pintar, recoger hojas, cortar pasto, etc?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
How many months did you do this activity? ¿Cuántos meses hizo esta actividad?	99 = Unknown
How many times per month did you do this activity? ¿Cuántas veces en el mes hizo esta actividad?	99 = Unknown
How long did you do this activity on average each time? En promedio ¿por cuánto tiempo hizo esta actividad cada vez?	Number of minutes 999 = Unknown
In the past 12 months for at least one hour total time in any month did you do En los últimos 12 meses, hizo por lo menos durante una hora en cualquier mes....	
Do non-strenuous weight training including free weights or machines such as Nautilus? ¿Levantar pesas o usar máquinas como Nautilus de forma no extenuante?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
How many months did you do this activity? ¿Cuántos meses hizo esta actividad?	99 = Unknown
How many times per month did you do this activity? ¿Cuántas veces en el mes hizo esta actividad?	99 = Unknown
How long did you do this activity on average each time? En promedio ¿por cuánto tiempo hizo esta actividad cada vez?	Number of minutes 999 = Unknown

Leisure Time **Tiempo de Relajación**

My next question is about Leisure Time

Mis siguientes preguntas son sobre tiempo de relajación

<p>In the past week, about how many hours per day did you sit and watch TV or videos?</p> <p>En la última semana ¿como cuántas horas al día se sentó a ver televisión o videos?</p>	<p>0 = None or < 1 hour 1 = 1 hour 2 = 2 hours 3 = 3 hours 4 = 4 hours 5 = 5 hours or more 9, Unknown</p>
<p>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?</p> <p>En la última semana ¿como cuántas horas al día usó la computadora (por placer) o jugó juegos en la computadora o video juegos?</p>	<p>0 = None or < 1 hour 1 = 1 hour 2 = 2 hours 3 = 3 hours 4 = 4 hours 5 = 5 hours or more</p>

Additional Comments

Physical Activity Questionnaire - Leisurely Activities

Form is intentionally left blank <input type="checkbox"/> checked = "Yes"	Check box
Reason why form was left blank _____	Character field
Technician Number _____ Select from drop down	Character field

If form was intentionally left blank none of the following questions would be asked.

Now, I'd like to ask you about more **WORK ACTIVITIES**. In the past year....

Ahora quisiera preguntarle más sobre **ACTIVIDADES EN SU TRABAJO**. En el último año...

Do you work? <input type="checkbox"/> ¿Trabaja?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
In the past year... En el último año.... How many hours per week do you work? ¿Cuántas horas a la semana trabajó?	Number of hours 999 = Unknown

For seasonal workers - Answer for the work you do most of the year.

Para quienes trabajan temporalmente – Conteste por el trabajo que haga la mayor parte del año.

In the past year... En el último año...	0 = Never Nunca (0 hrs)	1 = Seldom Poco	2 = Sometimes A veces	3 = Often Seguido	4 = Always Siempre	9 = Do not Recall No recuerda
At work do you SIT En el trabajo usted está SENTADO	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
At work do you STAND En el trabajo usted está DE PIE	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
At work do you WALK En el trabajo usted está CAMINANDO	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Additional Comments

Age at last exam	Calculated variable
Form is intentionally left blank	Check box
Reason why form was left blank	Character field
Technician Number	Character field

If form was intentionally left blank none of the following questions would be asked.

Respiratory Diagnoses Enfermedades Respiratorias

Since your last exam.... Desde su último examen...

Have you had asthma? Ha tenido asma?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
Do you still have asthma? ¿Todavía tiene asma?	0 = No; 1 = Yes; 9 = Unknown
Was the asthma diagnosed by a doctor or other health care professional ¿Fue diagnosticado por un doctor o profesional de la salud?	0 = No; 1 = Yes; 9 = Unknown
If asthma started since your last exam, at what age did it start? Si el asma empezó después de su último examen ¿a qué edad empezó?	Age in years 888 = If asthma started before last exam 999 = Unknown
If you no longer have asthma, at what age did it stop? Si ya no tiene asma ¿a qué edad paró?	Age in years 888 = Still have it 999 = Unknown
Have you received medical treatment for this in the past 12 months? ¿Ha recibido tratamiento medico para el asma en los últimos 12 meses?	0 = No; 1 = Yes; 9 = Unknown
Have you had any of the following conditions diagnosed by a doctor or other health care professional? ¿Ha sido diagnosticado por un doctor o profesional de la salud con...	
Chronic Bronchitis Bronquitis Crónica	0 = No; 1 = Yes; 9 = Unknown
Emphysema Enfisema	0 = No; 1 = Yes; 9 = Unknown
COPD (Chronic Obstructive Pulmonary Disease) Enfermedad Pulmonar Obstructiva Crónica	0 = No; 1 = Yes; 9 = Unknown
Sleep Apnea Apnea del Sueño	0 = No; 1 = Yes; 9 = Unknown
Pulmonary Fibrosis Fibrosis Pulmonar	0 = No; 1 = Yes; 9 = Unknown

Additional Comments

Respiratory Disease

Exit Interview and Adverse Events

Form is intentionally left blank	Check box
Reason why form was left blank	Character field
Technician Number	Character field

If form was intentionally left blank none of the following questions would be asked.

Exit Interview **Entrevista de Salida**

Removed and placed bar code label in chart?	0 = No 1 = Yes 2 = Bar code label not used 9 = Unknown
Referral sheet reviewed? ¿Le recomendó el doctor que viera a alguien como seguimiento?	0 = No; 1 = Yes; 9 = Unknown
Dietary questionnaire brought to Research Center? ¿Nos dió su cuestionario sobre la dieta?	0 = No (refused or forgot to bring at time of exam) 1 = Yes 2 = Sent home 9 = Unknown
Left center with medications and belongings? ¿Se lleva todo lo que trajo incluso sus medicinas?	0 = No; 1 = Yes; 9 = Unknown
Left center with accelerometer? ¿Lleva el acelerómetro?	0 = No, refused 1 = Yes 2 = Mailed to participant 9 = Unknown
Left center with stool microbiome kit? ¿Lleva el kit del microbioma?	0 = No, refused 1 = Yes 2 = Mail 9 = Unknown
If "Yes" or "Mail"	
Microbiome id number	Character variable
FHS Study ID for Broad	
<u>IPHONE</u> - Left center with eFHS app? ¿Va a hacer los estudios electrónicos on el iPhone?	0 = No, refused 2 = No, no iPhone 1 = Yes 3 = Will return later for set up 9 = Unknown
<u>ANDROID</u> - Left center with eFHS app? ¿Va a hacer los estudios electrónicos on el Android?	0 = No, refused 2 = No, no Android 1 = Yes 3 = Will return later for set up 9 = Unknown
Left center with TBI survey information? N/A	0 = No, refused 1 = Yes 9 = Unknown

Feedback
Check all that apply and supply comments

Feedback – NONE	Check box
Feedback – POSITIVE	Check box
Comment	Character field

Exit Interview and Adverse Events (cont)

Feedback – NEGATIVE	Check box
Comment	Character field
Feedback – OTHER	Check box
Comment	Character field

Adverse Events Eventos Adversos
(not requiring further medical evaluation) (que no requieren evaluación médica)

Technician Number	Character field
Was there an adverse event in center that does not require further medical evaluation?	0 = No; 1 = Yes; 9 = Unknown
If "Yes"	
Adverse Event comments	Character field
Technician who reviewed that all REDCap form questions were completed	Character field

Additional Comments

Exit Interview and Adverse Events

Su examen de hoy fué hecho sólo con propósitos de investigación médica y no está diseñado para diagnosticar.

Este examen no puede identificar todos los problemas cardiacos serios ni de su salud en general.

Es importante que continúe checándose con su doctor regularmente.

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.