



Healthy Aging in Neighborhoods of Diversity across the Life Span

Examination Visit

1

Protocol # 09-AG-N248, V.1-24-2017
OPS Approval Date 10/19/2017

Informed Consent Booklet

Introduction

We must have your written informed consent before we perform research tests or examinations.

We follow federal regulations for research with human subjects. These regulations require us to make sure that you understand what examinations we will perform and the risks that are involved, if there are any.

This booklet reviews the tests that we will perform in this research. We perform these tests free of charge. You should understand the purpose of this study before you agree to participate in this research. We welcome any questions that you might have about what to expect in this study. You may participate in any of the tests, but you need not participate in all of the tests. You may stop any time after a test starts. You may ask questions any time during a test.

We want to make sure that you understand the tests in this study. We must witness your signature on the consent form. Please do not sign the consent form until you arrive at the Mobile Medical Research Vehicles.

Purpose of the Study

The purpose of this study is to learn about changes in health over time in an urban, working and non-working group of African American and white, men and women residing in Baltimore city. We want to study as many people in different communities as we can by using our Mobile Medical Research Vehicles (MRVs).

Our goal is to study the rate of health change, as people grow older. We plan to do this by studying the same people over many years. This gives us the information we want about how people's bodies change over time. We will continue to invite you to participate in our study every three to four years when we visit your neighborhood with our Mobile Research Vehicles (MRVs).

We also want to study why some people are healthier as they get older than others. We want to discover if we can predict the causes of good health with aging. If we can find the causes of good health, then we might find the cures for some of the diseases related to aging.

We call our study *Healthy Aging in Neighborhoods of Diversity across the Life Span*.

We are currently conducting the fourth visit to your neighborhood. The study data will be collected in two parts. The first part of the study consists of a visit to the MRVs. The MRV-1 will be used for the medical history and physical examination, body composition & bone density, test of the heart's function, strength testing, a health literacy assessment and skin and

toenail sample collection. MRV-2 will be used for consenting, the dietary recall interview, questionnaires, and to administer the skin tone identification assessment, and cognitive, memory & sensory testing. MRV-3 will be used for consenting, initial medical screening and the collection of laboratory samples. You will begin your visit on MRV-2 for consenting and you will then have your screening and blood work on MRV-3. You will then proceed to either MRV-2 or MRV-1 depending on the schedule for the day. You will visit all three vehicles before the day is complete.

The second part of the study will be conducted as a telephone interview. You will be asked to complete another dietary recall interview just like the one you did on MRV-2 and includes the use of over-the-counter medications and dietary supplements.

List of Tests and Statements of Risk

We want you to understand the risks in taking some of these tests. We welcome your questions about the tests and any risks even after the test starts.

Risks, if any, are stated and discussed with the description of the test, or in the section on *Assessment of Risks* in this booklet.

Body Composition

We will weigh you and measure your height. There are no risks from this test.

Bone Density (DEXA)

We will measure the size and quality of the bones in your back and hip. We will also perform the instant vertebral assessment (IVA), which allows for screening of vertebral fractures. These measures will tell us if you are likely to have osteoporosis (thinning of the bones) – a risk factor for bone fractures. We will also measure how much lean tissue and fat tissue you have in your body.

We will ask you to lie down on a device called a DEXA scanner. The scanner uses small amounts of X-ray radiation to make measurements as a detector examines your body.

The risk to you, if any, is estimated to be slight. The risks are discussed in the section on *Assessment of Risks* in this booklet.

Muscle Strength Testing

The information we collect will help us to understand how strength changes as people get older.

Grip Strength Test

Handgrip strength in both hands will be measured using an adjustable, hand-held, hydraulic grip strength dynamometer. The hydraulic grip strength dynamometer is a device you hold in your hand and squeeze. It measures the strength of your handgrip.

You will be asked to sit with the arm to be tested resting on the table. The dynamometer is held in the hand to be tested and is resting on a mouse pad. We

will ask you to grip the two bars of the dynamometer in your hand, and to slowly squeeze the bars as hard as you can. The test is repeated on the other hand.

Exclusions. If you have had arm or hand surgery like fusion, arthroplasty, tendon repair, synovectomy, or other related surgery in the past 3 months you will not be tested on the affected hand.

Chair Stand

Using a standard armless chair placed securely against a wall, you be asked to rise from the chair without using your arms and to return to a seated position. If this is done successfully, you will be asked to repeat that movement 10 times.

Exclusions. There are no formal exclusions from attempting the single chair stand; inability to rise from a chair without using arms excludes participants from doing repeated chair stands.

Balance Test

We will ask you to stand with your feet together and with your feet in a heel-to-toe position for 30 seconds each. We will also ask you to try to stand on one leg for 30 seconds. You may stand on whichever leg is more comfortable. The examiner will demonstrate exactly what is expected. We will ask you to try to hold your foot up for thirty seconds. We will ask you to repeat this test 2 times.

We want you to know that there are very minimal risks associated with these tests. The only risks are that there is a slight risk of falling and you may feel tired after these tests.

Medical History and Physical Examination

Medical History

We will ask you questions about changes and updates to your medical history since your first MRV visit. The examiner will add information to the form when you have your physical examination.

Smoking, Drug and Alcohol History

We will ask you about your smoking habits and use of drugs and alcohol.

Physical Examination

Our physician or nurse practitioner will give you a physical exam in our private exam room. They will check your blood pressure and pulse in both arms. They will listen to your heart and lungs, examine your eyes, joints, and check your reflexes and other parts of your nervous system. The physician or nurse practitioner will also examine your abdomen.

Our physician or nurse practitioner will not do a complete physical exam. You should still see your personal physician for regular check-ups.

Skin swab and toenail sample collection

We will examine if you have been exposed to toxins or chemicals in the environment that might relate to your health and wellbeing. To study this, we will ask you for toe nail clippings from the tips of all 10 of your toes. The nurse practitioner or Doctor will use a stainless steel, single use nail clipper to collect a small sample from each toenail.

Risks. When clipping the toenails, there is a slight risk of minor injury to the nail cuticle with a risk for bleeding or infection.

We will study skin microbiome (the mix of bacteria, yeasts, and parasites that live on your skin) and how they interact with age and chronic disease and influence wound healing. We will collect a skin microbiome sample by rubbing a cotton swab on the skin of your arm.

There are no risks from this procedure.

Tests of your Heart Functions

We will do a test to see how well your heart functions. We will discuss the results with you after we finish the tests. If we find a heart problem, we will discuss the problem with you and we will send the results to your personal doctor if you want us to.

Resting Electrocardiogram (ECG)

We will place wires called electrodes on your skin to record your heartbeats. We will look at your heart rate and rhythm, electrical pulses of your heart, and check if you have an enlarged heart. We will check if you have had a heart attack or have any other heart condition.

There are no risks from this procedure.

Carotid Doppler Ultrasonography

We will ask you to lie down and rest for 10 minutes. We will place a small ultrasonic probe on your neck to take pictures of the artery in your neck and measure the thickness of this blood vessel.

There are no risks from this test. There is no radiation in this test. Ultrasound is not the same as an x-ray and does not involve any radiation.

Peripheral Arterial Tonometry: The EndoPAT test

The EndoPAT test measures the way the lining of your blood vessels work. This gives us a way to look for early signs of disease in the blood vessels that might lead to high blood pressure or to heart disease. We will put a blood pressure cuff on your arm and a small fingertip probe on each of your index fingers that allow us to measure blood vessel function without drawing blood or sticking you with a needle. In this test we will see how well you blood vessels relax after the blood pressure cuff is pumped up on your arm for 5 minutes.

You will rest on your back for 15 minutes while we do this test. There is little risk for this test. There is no radiation. The blood pressure cuff on your arm may make your arm feel as though it has fallen to sleep.

This will resolve on its own shortly after the test is over.

Nutritional Dietary Recall

During this interview, we will ask you to remember all the foods and beverages you have consumed during the last 24 hours. We will have some cups and measures to help you remember the amounts.

A trained interviewer will record your answers and ask questions designed to help you remember using a method developed by the United States Department of Agriculture (USDA).

The risks for the dietary recall interview are very minimal. The only risk of this part of the study is that you may become tired. All examiners who are involved in asking these questions are experienced in using these procedures and they will minimize any discomfort that you might feel.

Problem Solving and Memory Testing

We will ask you to do some tasks that exercise your thinking, decision making, and memory. These tasks may ask you to remember words, numbers, and pictures. These tasks also ask you to respond as quickly as you can and they will ask you move objects on a screen or to imagine how objects look in different positions.

The test for remembering is called the N-Back Test. The tests for words are called the Wide Range

Achievement Test and the Category Fluency Test. The test for comparing objects is called the Abstract Matching Test. The test for switching letters and numbers is called the Trailmaking Test. The test for imagining objects in different positions is called the Line Orientation Test. Other tests, called Mental Status Tests, measure several types of memory abilities. These tests are given in private with a tester who will help you understand how to do the best you can.

We want you to know that some people find these tests tiring. Sometimes, people feel nervous when they do these tests. The examiner who gives these tests is experienced in making sure you feel as little discomfort as possible. The tests are designed so everyone may find one or more of them difficult; no one gets a perfect score. You may stop testing any time you want if you are disturbed by the tests.

Sensory Testing

The Smell Identification Test (SIT) and *Sniffin' Sticks*

The purpose of the smell identification and *Sniffin' Sticks* tests is to see if we can find problems with the ability to identify smells. Sometimes problems with smell can be related to medical, psychological or brain conditions.

The SIT test is made up of 4 booklets with 10 scratch and sniff questions per book. You will be asked to scratch and sniff each item and to tell us what you smell.

The *Sniffin Sticks* system includes 3-6 smelling sticks that look like a pen. They are called odor pens. You will be asked to smell a number of odor pens and tell the examiner what you smell.

There are no known risks associated with either smell test. You may find some odors unpleasant but the smell will go away quickly.

Visual Acuity and Fundus Photography

The purpose of these tests is to learn more about Age-related Macular Degeneration (AMD), a condition that can develop as we age. We will also test your vision.

Fundus Photography - Photographs will be taken of the back part of your eye (fundus) with a special camera. You will see some flashing lights. The taking of photographs is not associated with any risk; however, the bright lights may cause temporary discomfort.

Visual Acuity Test: The study team will test your vision. Your visual acuity (reading letters on an eye chart) will be measured using a machine called a refractometer. These tests have no risk and will not cause discomfort. You will get a report of your results.

Skin Tone Identification Assessment

We will ask you to participate in a skin color identification assessment where we will ask you to look at pictures of different skin tones and select the one

that you think best matches yours. We want to see if there is a relationship between skin tone and discrimination.

There are no risks for this procedure.

Questionnaires

We will ask you to complete several questionnaires about your use of health care services, present health status, smoking behavior, your level of physical activity, your use of nutrition supplements and over-the-counter medicines, your neighborhood, income and other financial interests, mental health, household composition, if you provide care to others, education and employment.

These questionnaires will be filled out on the Mobile Research Vehicles by using a computer and headphones and/or by telephone interview. While on the MRV, we will help you do the questionnaires if you want us to. If you have trouble seeing or reading the questions you may ask one of our testers to help you. These tests are given in a private, quiet room.

Blood, Tissue, and Urine Sampling

If you agree, we will ask you to give us a blood sample and a urine sample. To prepare you for the blood tests we will ask you not to eat or drink anything after midnight the night before your visit to the MRVs. The blood draw will be performed right before you are served breakfast. We will use these samples to measure your health and so that we can measure

changes in your health if we test you again. We will measure your white and red blood cells, your cholesterol, salt, and sugar, and how well your blood carries oxygen through your body and how fast you heal from minor cuts. We will also measure blood chemistry that may tell us how well your body organs work, such as the heart, liver, and kidneys. Women between the ages of 30 and 55 years will get a pregnancy test. We will be testing for communicable diseases including Hepatitis B, Hepatitis C, and Syphilis.

You will be offered a test for HIV. If you decide to have the test, you will be asked to sign a separate consent form that explains the HIV testing procedures for the HANDLS study.

We will ask you to donate about 87.5 milliliters of blood (~6 tablespoons). For comparison, the Red Cross usually asks for a donation of about 500 milliliters of blood (about two cups).

The risk to you, if any, is estimated to be slight. The risks are discussed below in the section on *Assessment of Risks* in this booklet.

Buccal Cell Collection

As part of the medical evaluation buccal mucosa cells will be collected from you, if you agree, using the DNA Genotek Oragene RNA and DNA self collection system. This system collects buccal cells from inside your mouth by asking you to give a saliva sample by spitting into a small cup. The extracted DNA will be used for

epigenetic analysis. Epigenetic analysis lets us study chemical changes to the DNA that may also lead to changes in the way genes and cells in your body work.

There are no known risks associated with the DNA Genotek Oragene RNA and DNA self collection system (the saliva collection system using a cup).

If you are unable to provide a saliva sample we will use another method to collect the sample called the Whatman FTA collection system. You may remember we used the Whatman system during your last MRV visit. This system collects buccal cells using a foam tipped applicator. We will ask you to place the applicator into your mouth and rub on the inside of both cheeks for 30 seconds. You will then hand the applicator to staff and they will transfer the sample to a card and send it to the lab for analysis.

Buccal Mucosa smear (Watman FTA collection system) risks include irritation of the inside of the cheek and/or gum line by the foam tipped swab used to collect cells and saliva when using the Watman system.

Genetics/DNA Testing

Genes are composed of the genetic material called DNA. DNA (deoxyribonucleic acid) is the part of the cell that is responsible for providing hereditary characteristics (such as eye color) and is used to build proteins. More and more, we are discovering that our genes are important for understanding our health. Your genes are the parts of each cell inherited from your mother and father. Your

genes are what make you a unique individual. Genes are made from DNA. We want to use some of your donated blood to freeze your DNA. We are not sure what studies will use your DNA. New studies may look at how your genes affect age-related diseases. The risks associated with participating in genetics testing are discussed below in the section on *Assessment of Risks* in this booklet.

Future Use of Samples

Doctors often make new discoveries by testing blood and urine. We would like to freeze a portion of your blood and urine samples to save them in our frozen tissue bank. We are not sure what new discoveries will appear in the future. We want to set aside your samples until there are new tests that will help us understand health and aging.

The samples saved in our bank will be stored at very low temperatures. Unlike household freezers, these freezers can preserve samples for many years, perhaps many decades. We will label your samples with code numbers. Only the principal investigators in this study will know your code number. Only researchers in this study will know the results of tests using your genes. We will not reveal your results to anyone who is not associated with this research.

Results

We will ask you if you want the results of the tests that we perform on your blood and urine. We will also ask

you if you want us to send your results to your personal physician.

We do not plan to report the results of the studies we do on your genes because at this time, these tests do not diagnose or predict the development of specific diseases. In the future, we may offer you some of the results if the Food and Drug Administration approve some of the tests. Additionally, we will not report results for the environmental exposure or the skin studies as these tests are for research purposes only.

Assessment of Risks

Blood Sampling

We want you to know that there are some risks in donating a blood sample. The trained HANDLS staff member will insert a needle in a vein in your arm. There is a risk of an infection from the needle puncture. There is also a risk of a black and blue mark, and you may feel faint. These risks are very small. Our staff is well trained and has drawn blood many times. It is common to have a small black and blue mark, but it disappears after a day or so. Some people have begun perspiring, or they felt nauseated and their pulse slowed. None of them had any after effects.

Genetics Testing

You will be asked to be part of the study involving genetic testing. Risks of genetic testing include the misuse of personal, genetic information by people who

are not authorized to have this information. Although rare, misuse of such information has caused problems for persons related to employment, and life or health insurance benefits and rights. Although there can be no absolute guarantees, every reasonable effort will be made to keep your personally identifiable information secret so that there will be no misuse. Even when the information is kept secret, if you are asked if you have ever been tested for a genetic disorder, answering "yes" could cause benefits to be denied or could cause other problems including discrimination. There is a risk that being in a genetics study can cause psychological distress or tension with other family members if they do not want you to be in the study.

Radiation - Bone Density test (DEXA)

Each day everyone receives a certain amount of natural radiation from various sources in the environment, such as the sun. The exact amount of radiation is measured in units called millirems. The National Council on Radiation Protection and Measurements measures average radiation exposure. They estimate that people in our country receive 300 millirems of annual exposure.

The radiation you will receive from participating in this study is equivalent to an exposure of less than 1 millirem to your whole body or about as much radiation than the average person in our country receives in a day.

Please be aware that this radiation exposure is for research purposes only, and is not essential for your medical care. The NIH Radiation Safety Committee, a group of experts on radiation matters, has reviewed the use of radiation in this research study and has approved this use as being necessary to obtain the research information desired.

The radiation dose you will receive is within the NIH Radiation Safety Guidelines for research subjects. The potential long-term risk from the radiation doses in this study is uncertain, but these doses have never been associated with any definite adverse effects. Thus the risk to you, if any, is estimated to be slight.

Please advise your doctor if you have participated in research studies at the NIH or other institutions that involved the use of radiation so that it may be determined that the total radiation dose from all studies is not excessive. Examples of such studies include x-ray studies conducted in radiology departments, cardiac catheterization, and fluoroscopy as well as nuclear medicine studies, for example technetium and PET scans.

If you are female, you may participate in this study only if you are certain you are not pregnant. If you become pregnant (or suspect pregnancy) before the study is completed, you must inform the investigator.

You are participating in a research study and our physicians and technicians are not your primary health-care providers. We will provide medical feedback to

you and, with your permission, to your personal physician about your health based on the tests in which you participate. If you need a referral to a physician, we will provide a list of local physicians and assist you in locating a health care provider in your area if you like.

If you have any questions about the study or the specific procedures or risks, please ask the HANDLS study staff members. They will be happy to answer any questions you may have at any time during the study.

**APPROVED FOR USE
FROM OCTOBER 05,2017 THROUGH OCTOBER 04,2018**