

Healthy Aging in Neighborhoods of Diversity across the Life Span



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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. We want to study as many people in

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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 second 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-I will be used for the medical history and physical examination, body composition, test of the heart's function, strength testing and bone density. MRV-II will be used for the dietary recall interview, questionnaires, and to administer the cog-

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nitive and memory testing. MRV- III will be used for consenting, initial medical screening and the collection of laboratory samples. You will begin your visit on MRV-3 for consenting, screening and blood work. 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 phase of the study will be conducted as a telephone interview and includes 2 questionnaires. First, you will be asked to complete another dietary recall interview including the use of dietary supplements. Then we will ask you complete another questionnaire that asks about your use of health care services, present health status, your level of physical activity, your neighborhood, mental health, household composition, if you provide care to others, and any income and/or employment changes since your last visit to the MRVs.

We plan to continue to administer similar tests every three to four years for the next 20 years.

List of Tests and Statements of Risk

You may participate in some or all of our tests. You may stop any test anytime you want even after you agree to do it.

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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 various parts of your body. There are no risks from this test.

Bone Density

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.

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Muscle Strength Testing

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.

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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.

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

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

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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.

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.

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Echocardiogram

An Echocardiogram is an ultrasound test that is used to examine the structure and function of the heart. We will measure the size of the chambers of the heart, the thickness of the walls, and the function of the chambers as the heart pumps. We will also examine how well the heart valves work as they open and close.

An ultrasound sensor is placed on the chest, over the heart. The echo sound waves produce images on the monitor. These images show the action of the chambers and valves of heart.

The only possible risk from this procedure is irritation from the electrodes placed on the skin.

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).

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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 and memory. These tasks ask you to remember words, numbers, and pictures. These tasks also ask you to find similar words or to think of words beginning with certain letters or belonging to certain categories. They will also ask you to imagine how objects look in different positions.

The tests for remembering are called the Benton Visual Retention Test, the California Verbal Learning Test, and the Digit Span 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 Identical Pictures Test. The test for switching letters and numbers is called the Trailmaking Test. The test for imagining objects in different positions is called the Card Rotations Test. Other tests, called Mental Status Tests, measure several types of memory abilities.

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These tests are given in a private, quiet room 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. All examiners who are involved in giving these tests are experienced in using these procedures and they will minimize any discomfort that you might feel. If the tests are disturbing you, then you may stop testing any time you want.

Questionnaires

We will ask you to complete several questionnaires about your use of health care services, present health status, your level of physical activity, 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 head-phones and during the telephone interview as part of phase 2. 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.

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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.

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

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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.

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.

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 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

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genes. We will not reveal your results to anyone who is not associated with this research.

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.

We will ask you to donate about 62 milliliters of blood (about 4 1/2 tablespoons). For comparison, the Red Cross usually asks for a donation of about 500 milliliters of blood (about two cups).

Compensation

You will be paid up to \$220 (\$160 for the MRV visit and \$60.00 for the telephone interview) for participating in this study. You will receive a portion of the payment at the end of each phase. You will receive your payment in the form of an ATM debit card at the end of the each phase. If you do not perform all of the tests you will receive a portion of the payment. The ATM card will be activated before you leave the vehicle. You will be able to take the card to an ATM machine

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in your neighborhood to withdraw your payment. We will provide round-trip transportation from your home to our mobile testing center if you want it. We will serve a box breakfast and box lunch if you are participating in tests during mid-day. We will do our best to meet your dietary needs if you have any.

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.

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

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perspiring, or they felt nauseated and their pulse slowed. None of them had any after effects.

Buccal Cell Collection

As part of this study, you will be asked to sign a separate consent form to be in the part of this study involving genetic testing. Risks of genetic testing include the misuse of personal, genetic information. Although rare, misuse of such information has caused problems for persons related to employment, life, or health insurance benefits and right. There is a risk that being in a genetics study can cause psychological distress or tension with other family members. 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.

Radiation

Each day everyone receives a certain amount of natural radiation from various sources in the environment. The exact amount of radiation is measured in units called millirems. The National Council on Radiation Protection and Measurements measures average

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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. This whole body dose is called the effective dose. The average annual background radiation in the United States is an effective dose of 300 millirems per year. The amount of radiation in this study is equal to the background radiation in about one day. Using the standard way of describing radiation dose, you will receive 9.4 millirems to the skin over your lower spine and hip area, and total body. Thus, your body will receive a small dose of radiation.

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, that is, the effective dose is less than 5000 millirem in one year. 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

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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.

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

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