



Healthy Aging  
in  
Neighborhoods of  
Diversity across the  
Life Span

Home Visit  
Informed Consent Booklet



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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 have a witness of your signature on the consent form. Please do not sign the consent form until the HANDLS staff reviews the consent form with you, either in your home or over the phone. If we review the consent form over the phone you must have someone available to sign as the witness.*

## **Purpose of the Study**

The purpose of this study is to learn about changes in health over time in 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). If you are unable to come to the MRVs to have your examination visit due to physical limitations, we will visit you in your home.

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 examination visits in your neighborhood. The study will be conducted in your home, if you agree. The HANDLS medical staff will provide testing. During this visit you will be asked to provide an update about your medical history since your last HANDLS examination and you will receive a physical examination and a test to see how well your heart functions. We will assess your muscle strength and test your memory. We will ask you to complete sensory and health literacy testing and to answer a questionnaire. We will also take blood, tissue and urine samples. We will also test you for COVID-19 by collecting cells from your nasal passages using special swabs. We will collect 2 samples. One sample is for the rapid COVID-19 test; the BD Veritor SARS-CoV-2 test that will give a result in 20 minutes. The other sample will be sent to the lab for a PCR analysis.

Additional tests that are new for this visit include examining whether 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 toenail clippings from the tips of all 10 of your toenails. 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. To study this, we will collect a skin microbiome sample by rubbing a cotton swab on the skin of your arm.

### **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. 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 in this booklet.

#### ***Body Composition***

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

#### ***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. The blood draw will be performed at the beginning of your examination. 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. 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 87.2. milliliters of blood (about 6 tablespoons). For comparison, the Red Cross usually asks for a donation of about 500 milliliters of blood (about two cups).

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.

### *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 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 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 first 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

4

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 (the Whatman collection system using an applicator) 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 Whatman system.

### *COVID -19 Testing*

We will perform 2 tests for the corona virus (COVID-19) using a test called Nasopharyngeal Swab for SARS-CoV-2. One test is a rapid test that we will perform while we are in your home at the beginning of your visit. You will have results within 20 minutes. It is called the BD Veritor Test. The other test is the PCR assay test for SARS-CoV-2 that will be sent to a separate laboratory. Using a long swab, that we place in your nose, we will collect cells from inside your nose to test for the COVID-19 virus. If you test positive for COVID -19 on the rapid test, we will end your visit early for that day and ask you to stay home to recover. We will contact you again for another appointment. If your PCR test is positive, your name and contact information will be reported to the local health department as required by Maryland law.

The risks for the Nasopharyngeal Swab for SARS-CoV-2 (COVID-19) is mild discomfort and/or temporary irritation of nose canal. If you have had recent nose trauma or surgery, you will not have this test.

### *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.

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. 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.

### *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. The key to the ID number is kept in a separate, secure area to which only the clinical study staff have access. 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*

You will receive a Participant Report Packet in the mail, with results of your examination visit. If your study results indicate any medical condition or problem, the information will be provided to you and your doctor, if you authorize it.

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.

### ***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.

## ***Medical History and Physical Examination***

### *Medical History*

We will ask you questions about changes and updates to your medical history since your last study 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. 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.

There is minimal risk associated with the medical history and physical examination. Some of the questions may make you feel uncomfortable. You have the right to skip any question you do not wish to answer.

### *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 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.

## ***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.

The test for switching letters and numbers is called the Trailmaking 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 purpose of the *smell* identification test 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. You will have either the sniffin'sticks test or the Brief Smell Identification Test.

### *Sniffin' Sticks*

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.

### *The Brief Smell Identification Test (BSIT)*

The BSIT consists of 1 booklet with 12 scratch and sniff items per book (1 odorant per page; 12 questions total). To take this test, you will be asked to scratch the label on the page with a pencil, sniff it, and identify the odor.

*Exclusions.* There are no known risks associated with either smell test. You may find some odors unpleasant, but the smell will go away quickly. If you have trouble smelling or cannot smell at all, you will not be giving the smell test.

## ***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.

### **Questionnaires**

We will ask you to complete a questionnaire about your use of health care services, your experience with the COVID-19 pandemic, memory concerns, experience with gun violence, present health status, whether you have joint pain and/or stiffness, your level of physical activity, happiness, 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.

There is minimal risk associated with the questionnaires. Some of the questions may make you feel uncomfortable. You have the right to skip any question you do not wish to answer. All examiners who are involved in giving these questionnaires are experienced in using these procedures and they will minimize any discomfort that you might feel. If the questions are disturbing you, then you may stop testing any time you want.

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



