PRINCIPAL INVESTIGATOR: Michele K. Evans, M.D.

STUDY TITLE: Healthy Aging in Neighborhoods of Diversity across the Life Span (HANDLS) – Wave 7 Home Visit

STUDY SITE: Neighborhoods of Baltimore city

Cohort: Healthy volunteers

Consent Version: 2/22/2022

WHO DO YOU CONTACT ABOUT THIS STUDY?

Principal Investigator: Michele K. Evans, M.D., p: 410-558-8573
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Lead Associate Investigator: Alan B. Zonderman, Ph.D, p: 410-558-8280
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This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at the National Institutes of Health (NIH). Members of the study team will talk with you about the information described in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). Take the time needed to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers. Taking part in research at the NIH is your choice.

If the individual being asked to participate in this research study is not able to give consent to be in this study, you are being asked to give permission for this person as their decision-maker. The term "you" refers to you as the decision-maker and/or the individual being asked to participate in this research, throughout the remainder of this document.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

We invite you to take part in the next phase of a National Institute on Aging (NIA) research study called Healthy Aging in Neighborhoods of Diversity across the Life Span (HANDLS). You were selected as a participant in this study because several years ago when we were looking for residents from your neighborhood, you decided you wanted to take part in the study. It is time for us to return to your neighborhood for the third follow-up examination. You now have an opportunity to decide whether you would like to participate in the next phase of HANDLS. You will notice that some of the tests are the same as the last time we saw you. We have added some different tests and questionnaires that you might not be familiar with. Please take your time to read this form.

WHY IS THIS STUDY BEING DONE?

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. Our goal is to study health change, as people grow older. We plan to do this by studying many people in different neighborhoods and the same people over many years. This gives us the information we want about how peoples' bodies change over time.

We also want to study why some people are healthier than others as they get older. We want to discover if we can predict the causes of good health with aging and if we can find better ways to prevent and treat disease. If we can find the causes of good health, then we might find cures for some of the diseases related to aging. In this study, we will follow you for a total of twenty years to see how you age. This will help us learn about diseases like heart disease, Alzheimer's disease, high blood pressure, diabetes and stroke. We are trying to understand why some Americans have higher rates of certain diseases and more severe diseases than other Americans.

The nature of the study, the benefits, risks, discomforts and other information about the study are discussed further below. If any new information is learned, at any time during the research, which might affect your participation in the study, we will tell you. We urge you to ask any questions you have about this study with the staff members who explain it to you and with your own advisors before agreeing to participate.

WHO CAN PARTICIPATE IN THIS STUDY?

To be eligible for this research study the following must apply:

- You must have agreed to participate in Wave 1 of the HANDLS study;
- You must have one form of government issued identification

ARE THERE ANY REASONS I SHOULD NOT PARTICIPATE?

You will not be able to participate in this research study if any of the following apply:

- You were not enrolled in Wave 1 of the HANDLS study;
- You are pregnant;
- You are currently undergoing cancer treatment (chemotherapy or radiation)

WHAT IF I AM PRESENTLY PARTICIPATING IN ANOTHER RESEARCH STUDY?

Are you presently participating in any other research studies? Yes ☐ No ☐

If yes, please state which study (ies) _____

While participating in this study, you should not take part in any other research project that in the judgment of the principal investigator is incompatible with this research study. This is to protect you from possible injury arising from such things as extra blood drawing, extra x-rays, interaction of research drugs, or similar hazards.

WHAT HAPPENS IF I AGREE TO BE IN THE STUDY?

The HANDLS Wave 7 study data will be collected as part of the examination visit that requires you agree to have the HANDLS medical staff come to your home to provide testing. The second part of the study is made up of two sub-studies; the HANDLS scan sub-study, conducted at the University of Maryland and the Predictors of Personality (POP) sub-study conducted out of Florida State University. You will learn more about the optional sub-studies at the end of your examination visit or by receiving a telephone phone call, if you are eligible to participate.

This is the consent form for HANDLS Wave 7 Home Visit. You will be asked to give your consent for all the procedures and interviews that make up Wave 7 of HANDLS. Specifically, we want to be sure you understand the nature of the research we are doing and what is being requested of you. It is also important that you understand any potential risks to you.

You may participate in any of the tests, but you do not have to participate in all of the tests. Choosing not to participate in a test will not affect your right to participate in the rest of this study. You may stop any test after it starts. If you are unable to complete all of the tests in one visit, our staff may return to your home to complete your testing. All of the tests are performed for the purpose of research and are not designed to improve your health at this time. There are no experimental medications, tests or procedures in this study. We perform these tests free of charge.

Prior to the in-home examination visit you may be asked to participate in a telephone or videocast appointment that is designed to reduce the time study staff will spend at your home examination visit. During the telephone or video conference study staff will go over the informed consent procedures and your willingness to participate in the next examination visit. If you agree, we will also collect information about your medical history since your last examination visit and ask you questions about activities of daily living, your experience during the COVID pandemic, smoking behavior, memory concerns, use of health care services, experience with gun violence and any income and/or employment changes since your last visit. We will also ask questions about whether you experience joint pain and stiffness. If you participate in the telephone interview we will not repeat the procedures as listed below for the full home examination visit.

During the home visit, you will be asked to provide an update about your medical history since your last 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. If you agree, we will ask you to give us a blood, tissue and urine sample. 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 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).

New this wave, we will administer sensory testing that will include a smell identification test. If you know you have trouble smelling or if you cannot smell at all, you will not be given the smell identification test.

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 toe nail 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.

We will also test you for the corona virus (COVID-19). We will do two tests using cells from your nasal passages. The first test, the BD Vertior System for rapid detection of SARS-CoV-2, can tell us within 20 minutes if you are positive for the corona virus. This will help us decide if it is safe to continue your visit. The second test is a PCR test for SARS-CoV-2 that will be sent to a laboratory. You will be informed of the results for the BD Veritor rapid test during your visit. You will receive results for both laboratory COVID tests within 24 hours of the study clinician receiving the results. If you test positive for the Nasopharyngeal swab your name and contact information will be reported to the local health department as required by Maryland law.

You will be asked to give a DNA sample by providing a blood sample and by using a method that collects cells from a saliva (spit) sample you provide. Before you agree to give the DNA sample please review the information below that explains the possible risks of providing DNA samples.

DNA (deoxyribonucleic acid), the part of the cell that is responsible for providing hereditary characteristics (such as eye color), provides information for building proteins. Genes are composed of DNA. More and more, we are discovering that our genes are important for understanding our health. We will study genes and parts of genes that may cause age related diseases or make these diseases more severe. By finding out the genes that cause specific conditions associated with aging, we may be able to find ways to prevent certain diseases, find them at an earlier and milder stage, or at least be able to treat these conditions better. This study is particularly interested in genes that may be involved with loss of memory, high blood pressure, heart disease, stroke, cancer, diabetes, and arthritis.

As part of this study, you will be offered a test for the human immunodeficiency virus (HIV). This is the virus that causes AIDS. If you are infected with HIV, you will still be able to participate in this study. We will tell you what the results mean, how to find care, how to avoid infecting others, how we report newly diagnosed HIV infection, and the importance of informing your partners of

the possible risk because of your HIV infection. If you decide to have the test, you will be asked to sign a separate consent form. It will explain the HIV testing procedures for the HANDLS study.

Below is a table that shows the tests you will be expected to complete. This chart also tells you how long we think it will take each test to be done and what procedures are included in telephone or videoconference.

HANDLS Wave 7 – Home Visit Examination

Measure or Procedure	Estimated Timing
**Consent (completed by phone or in-person)	20 minutes
BD Veritor Sys for rapid detection of SARS-CoV-2	20 minutes
Specimen Collection*, Vitals and EKG	45 minutes
Cognition & sensory testing (smell)	60 minutes
**Interim Medical History	30 minutes
Interim Physical Exam	45 minutes
Skin & toenail sample collection	10 minutes
Hand Grip	10 minutes
**Questionnaires	15 minutes
Health Literacy	10 minutes
*Includes Nasopharyngeal Mucosa Swabs	

**Includes procedures that may be administered by telephone or videoconference prior to the examination visit.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

About 3720 people will take part in this study.

ARE THERE RISKS AND SIDE EFFECTS OF THIS STUDY?

The potential risks for this study are minimal. 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 after providing a blood sample, or they felt nauseated and their pulse slowed. However, these effects went away quickly.

You should be aware that the COVID tests we are using; the Hologic Panther Fusion SARs CoV-2, the Abbott Architect and the BD Veritor System for rapid detection of SARs-CoV-2 have been

authorized by the FDA for emergency use only (EUA) under an Emergency Use Authorization. These tests are investigational and are not approved by the FDA.

The risks for the BD Veritor System for rapid detection of SARS-CoV-2 and 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.

Risks from a false negative COVID test result include delay in treatment, lack of monitoring for symptoms resulting in increased risk of spread of COVID-19.

The risk of genetic testing (by providing the DNA sample) includes the possible 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 it will not be misused. Additionally, there is a risk that being in a genetics study could cause psychological distress or tension with other family members if they do not want you to be in the study.

For the environmental exposure testing, when clipping toenails there is a slight risk of minor injury to the nail cuticle with a risk for bleeding or infection.

The risks for the questionnaires and memory & sensory testing are minimal. The only risk of this part of the study is that you may become tired and 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.

For more information about risks and side effects, you should call the Principal Investigator, Michele K. Evans, M.D. at 410-558-8573.

WILL YOUR SPECIMENS OR DATA BE SAVED FOR USE IN OTHER RESEARCH STUDIES?

As part of this study, we are obtaining specimens and data from you. We plan to use these specimens and data for studies going on right now, as well as studies in the future. These studies may provide additional information that will be helpful in understanding health disparities in aging or other diseases or conditions. This could include studies to develop other research tests, treatments, drugs, or devices that may lead to development of a commercial product by the NIA or its research or commercial partners. There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you. By agreeing to let us use your specimens and data, you give the NIA any rights you may have to the specimens and data.

Please place your initials in the blank next to Yes or No for the question below:

My specimens and data may be stored and used for future research as described above.

_____ Yes _____ No

Initials Initials

Research records will be kept using secure computers. These are password protected and maintained on a secure server with access limited to authorized NIA staff members. All NIA investigators and NIA staff members who have access to these databases have the proper training on patient privacy as well as the required Human Subject Protection Training.

Clinical laboratory records are kept by the NIA on secure computers. Only staff associated with your care have access to these results.

Your samples will be stored in freezers at a secure NIA facility. The sample is identified with your study ID, visit number and date. The key to the ID number is kept in a separate, secure area to which only the clinical study staff have access.

How long will your specimens and data be stored by the NIA?

Your specimens and data will be stored by the NIA indefinitely.

Risks of storage and sharing of specimens and data

When we store your specimens and data, we take precautions to protect your information from others that should not have access to it. When we share your specimens and data, we will do everything we can to protect your identity, for example, when appropriate, we remove information that can identify you. Even with the safeguards we put in place, we cannot guarantee that your identity will never become known or someone may gain unauthorized access to your information. New methods may be created in the future that could make it possible to re-identify your specimens and data.

DISCUSSION OF FINDINGS

New information about the study

If we find out any new information that may affect your choice to participate in this study, we will get in touch with you to explain what we have learned. This may be information we have learned while doing this study here at the NIH or information we have learned from other scientists doing similar research in other places.

WILL I BE GIVEN MY STUDY RESULTS?

You will receive a Participant Report Packet in the mail, with results of your home 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. To authorize the reporting of results to your physician you will need to sign a form called “Release of Medical Information”. You will be asked to sign this

form only if you want us to communicate with your physician. The study doctors do not provide medical treatment.

The genetic testing, environmental exposure (toenail clippings) and skin studies that will be done as part of this study are for research purposes only and you will not be given the results.

EARLY WITHDRAWAL FROM THE STUDY

The study doctor or the National Institute on Aging may stop your participation in this study at any time without your consent. This could happen if we feel it is unsafe for you to continue in the study or if you are no longer eligible to participate. Any information (data) or blood collected until that point in time would remain part of the study.

You can stop participating at any time. However, if you decide to stop participating in the study, we ask you to talk to the researcher and your regular doctor first.

COMPENSATION, REIMBURSEMENT, AND PAYMENT

Will you receive compensation for participation in the study?

Some NIH studies offer compensation for participation in research. The amount of compensation, if any, is guided by NIH policies and guidelines.

You will receive $240.00 for the examination visit that takes place in your home, including the initial telephone or videoconference (if you have one). Your payment will be made in the form of an ATM debit card at the end of the visit. If you are unable to complete all of the tests you may receive a portion of the payment. If we have to return to your home to complete testing on another day, you could be compensated for the additional visit**.** The ATM card will be activated within 24 hours of your visit. You will be able to take the card to an ATM machine in your neighborhood to withdraw your payment.

If you are eligible and decide to participate in either of the sub-studies, you could receive an additional $50.00 for the HANDLS scan sub-study and/or an additional $40.00 retail gift card for participating in the Predictors of Personality sub-study.

With few exceptions, study compensation is considered taxable income that is reportable to the Internal Revenue Service (IRS). A “Form 1099-Other Income” will be sent to you if your total payments for research participation are $600 or more in a calendar year. If you have unpaid debt to the federal government, please be aware that some or all of your compensation may be automatically reduced to repay that debt on your behalf.

Will you receive reimbursement or direct payment by NIH as part of your participation?

Some NIH studies offer reimbursement or payment for travel, lodging or meals while participating in the research. The amount, if any, is guided by NIH policies and guidelines.

This study does not offer reimbursement for, or payment of, travel, lodging or meals.

Will taking part in this research study cost you anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH.

You do not have to pay anything to be in this study. However, if taking part in this study leads to procedures or care not included in the study, it may lead to added costs for you or your insurance company. You will not be charged for tests that are part of this research study.

CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

A description of this study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your medical information be kept private?

We will make every effort to protect your personal information to the extent allowed by law. Medical records of research study participants are stored and used according to legal rules. Your personal information will not be included in any reports or publications resulting from this study.

As you know, when you first enrolled in the study we asked you for your social security number because we needed it to process your payment. If you do not want us to have your social security number you do not need to provide it, however, we may not be able to pay you for your participation.

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board
- HANDLS collaborators

When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

If we share your specimens or data with other researchers, in most circumstances we will remove your identifiers before sharing your specimens or data. You should be aware that there is a slight possibility that someone could figure out the information is about you.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical records we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your medical record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

POLICY REGARDING RESEARCH-RELATED INJURIES

NIA will provide short-term medical care for any physical injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, NIA, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

A Declaration under the Public Readiness and Emergency Preparedness (PREP) Act was issued by the Secretary of the United States Department of Health and Human Services on March 10, 2020. This Declaration limits the legal rights of a subject participating in clinical studies utilizing COVID-19 countermeasures. Because this study is covered by the PREP Act Declaration, covered persons, such as the manufacturers, study sponsor, researchers, healthcare providers and others have liability immunity (that is, they cannot be sued by you or your family under the laws of the United States).

If you believe that you may have been harmed as a result of this research study, certain claims for serious injury or death caused by the countermeasure may be eligible for compensation through the Countermeasures Injury Compensation Program. This is a program set up by the United States Government. Information about this program can be found at https://www.hrsa.gov/cicp/about/index.html or by calling 1-855-266-2427.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Michele K. Evans by email: me42v@nih,gov or telephone 410-558-8573. You may also call the Clinical Director Josephine Egan at (410) 350-3922; the NIA Clinical Research Protocol Office at (410) 350-3947, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again.

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

Signature of Research Participant	Print Name of Research Participant	Date

Legally Authorized Representative (LAR) for an Adult Unable to Consent: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I am legally authorized to make research decisions on behalf of the adult participant unable to consent and have the authority to provide consent to this study. As applicable, the information in the above consent was described to the adult participant unable to consent who agrees to participate in the study.

Signature of LAR	Print Name of LAR	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness should sign below if either:

1. **A short form consent process has been used to enroll a non-English speaking subject or**
2. **An oral presentation of the full consent has been used to enroll a blind or illiterate subject**

Witness:

Signature of Witness*	Print Name of Witness	Date

***NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:**

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated

the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: _____.