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

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

STUDY SITE: NIH NIA Baltimore

Cohort: Healthy Volunteers - Home Visit

Consent Version: 09/16/2024

WHO DO YOU CONTACT ABOUT THIS STUDY?

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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 next 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.

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. You may also be invited to participant in one of the sub-studies that are part of HANDLS. The first sub-study is conducted at the University of Maryland and is called HANDLS Scan. The second sub-study called Predictors of Personality is conducted at Florida State University and will take place over the telephone. You may also be invited to participate in the HANDLS Sleep Study that is conducted at the Clemson University. You will learn more about the HANDLS sub-studies during this examination visit or by receiving a telephone call, or letter if you are eligible to participate. You will be asked to sign a separate consent form if you decide to join a sub-study.

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. If you agree, we will 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, we will ask you to give us a blood, tissue and urine sample. Most of the samples that we collect will be used for clinical lab tests like ones you can get at a clinic or hospital. 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).

We will test you for the coronavirus (COVID-19). We will first test you by using the BD Vertior System for Rapid Detection of SARS-CoV-2, which can tell us within 20 minutes if you are positive for the coronavirus. If the BD Veritor System is unavailable, we will use the Flow*flex* COVID-19 Antigen Home Test. This will help us decide if it is safe to continue your visit. During the specimen collection procedures, we will also collect a sample of cells to send to the laboratory using a test called the Hologic Panther Fusion SARS-CoV-2 assay. These tests collect cells from the nasal passages. We will use a special nose swab to collect these cells from inside your nose. We will also test your blood for antibodies for the COVID infection using the Roche Diagnostics Elecsys Anti-SARS-CoV-2 immunoassay. You will be informed of the results for the BD Veritor Rapid test during your visit. You will receive results for the Panther Fusion test within 24 hours of the study clinician receiving the results. If you test positive, your name and contact information will be reported to the local health department as required by Maryland law.

As part of your participation in the HANDLS study, we would like to use copies of your medical records that are available through the Chesapeake Regional Information System for our Patients (CRISP). CRISP is a health information exchange that supports the sharing of patient health information among health care providers such as doctors, hospitals, laboratories, radiology centers, and other health care providers or facilities in Maryland, the District of Columbia, and other parts of the Mid-Atlantic region. More information about CRISP, including information about your right to decline to make your medical records available through CRISP can be found at www.crisphealth.org. To allow HANDLS access to your CRISP information we will need your permission which you can provide by initialing your response below. You understand that, if you decline HANDLS access to your information in CRISP, CRISP will not be able to provide data for the purpose of this research study. Even if you decide not to allow HANDLS access to CRISP you may still participate in the study.

The HANDLS study investigators have permission to access to my health information through CRISP:

_____ Yes _____ No

Initials Initials

Some of the blood specimens that you donate will be used to measure DNA and RNA, which are used for specific types of genetic testing. We will study your DNA by doing genetic tests that examine every gene in your DNA, looking for changes in your genetic code. This is called whole genome sequencing. Some genetic changes may cause disease, while other changes have no effect on health or cause disease. DNA are molecules that hold your genetic information. For example, different genes are responsible for hair and eye color. Genes may tell us if you have a higher or lower risk for some disease. Some of the samples will be used for research tests to understand the genetics of aging and chronic diseases like diabetes, dementia, high blood pressure and how they cause more death and disease in minority and poor people. Since these tests are for research, the results will not be given to you or your doctor. More research may be necessary to know for sure that these results are meaningful in terms of health and disease. If you do not want us to collect samples for genetic research, it does not mean that you cannot be a part of the HANDLS study.

My specimens may be used to conduct genetic research:

_____ Yes _____ No

Initials Initials

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.

You will have an EKG to measure your heart function, and we will take your blood pressure.

You will be asked to update your medical history since your last study visit and you will receive a physical examination. We will assess your muscle strength and test your memory.

We will also ask you to complete a questionnaire and to participate in health literacy and sensory (smell) testing. If you know you have trouble smelling or if you cannot smell at all, you will not be given the smell identification test.

New this wave, 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 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.

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 will be included in the telephone or videoconference.

HANDLS Wave 7 – Home Visit Examination

Measure or Procedure	Estimated Timing
BD Veritor Sys for Rapid Detection of SARS-CoV-2 or the Flow*flex* COVID-19 Antigen Test	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.

WHAT ARE THE 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 have 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 3 of the COVID-19 tests that we are using: the Hologic Panther Fusion SARs-CoV-2, the Roche Diagnostics Elecsys Anti-SARS-CoV-2 immunoassay, and the BD Veritor System for Rapid Detection of SARs-CoV-2 have been authorized by the FDA under an Emergency Use Authorization (EUA). 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, the Flow*flex* COVID-19 Antigen Test and the Hologic Panther Fusion for SARS-CoV-2 assay are 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-19 test result include delay in treatment and a lack of monitoring for symptoms resulting in an increased risk of spread of COVID-19.

The risk of genetic testing (by providing the DNA sample) includes the possible misuse of your genetic information by people who are not authorized to have this information, if it was accidently released. Although there can be no absolute guarantees, every reasonable effort will be made to keep your personally identifiable genetic information secret, so that it cannot be misused.

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 test of your grip strength has minimal risks. If you have had surgery on your hand or wrist in the last 3 months, you will not be given this test.

The risks for the questionnaires, health literacy 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.

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR SPECIMENS AND DATA

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.

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

_____ Yes _____ No

Initials Initials

Will your specimens or data be shared with other researchers for use in other studies?

We may share your specimens and data with other researchers. The other researchers may be doing studies in similar areas to this study or in other unrelated areas. These researchers may be at NIH, other research centers and institutions, or at commercial entities.

One way that we may share your data is by putting it into a large database called a repository, which is a way to make it widely available to the research community. If we do place your data in a repository, it will be labeled with a code, (not with your name or other information that could be used to easily identify you). Even though it will only be labeled with a code, some types of data, in particular data about your genes (called genetic or genomic data), can be used to figure out who you are, although this is difficult to do, and we think it is unlikely to happen.

The data in the repository will only be available to qualified researchers. These researchers must receive permission before they are allowed to access the data. Before receiving the data, the researchers must promise that they will not try to figure out the identity of the research participants.

If we do share your specimens or data, we will know that the specimens and data came from you. However, the other researchers will not know that they came from you (i.e., they will be de-identified).

Information about all the people (including you) in this study may be combined to create what is called summary information. The summary information may be placed in a database and shared in scientific publications. This information will help the researchers understand if some patterns are more common than others among everyone who was a part of this study. The summary information will be available to anyone without the need for any permission. The risk of anyone identifying you based on this information is very low.

Can you change your mind about use and sharing for future research?

If you change your mind and do not want us to store and use your specimens and data for future studies, you should contact the study team. We will do our best to comply with your request but cannot guarantee that we will always be able to destroy your specimens and data. For example, if some research with your specimens and data is already complete, the information from that research may still be used. Also, if the specimens and data have been shared already, it might not be possible to withdraw them.

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. 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.

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.

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 any of the sub-studies, you could receive an additional $100.00 for the HANDLS scan sub-study and/or an additional $40.00 Tango gift card for participating in the Predictors of Personality sub-study. The HANDLS Sleep Study provides $100.00 per study visit (a total of 4 visits over 4 years) and an additional $100.00 in the 4th year for completing the 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?

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

The researchers conducting this study and the NIH follow applicable laws and policies to keep your identifying information private to the extent possible. However, there is always a chance that, despite our best efforts, your identity and/or information about your participation in this research may be inadvertently released or improperly accessed by unauthorized persons.

In most cases, the NIH will not release any identifiable information collected about you without your written permission. However, your information may be shared as described in the section of this document on sharing of specimens and data, and as further outlined in the following sections.

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.

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, me42v@nih,gov, 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: _____.