

IRB number: 2009-149

Clinical Site Version: 08/01/2011

Project Title: Healthy Aging in Neighborhoods of Diversity Across the Life Span – Wave 3

Principal Investigator: Michele K. Evans, MD

Institution: National Institute on Aging, NIH

Informed Consent for Clinical Research HANDLS Wave – 3

SPONSOR: NATIONAL INSTITUTE ON AGING, NIH

SITE: Mobile Medical Research Vehicles (MRVs)
Neighborhoods in Baltimore City

INTRODUCTION

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 when we were looking for residents from 30 and 64 years old in your neighborhood you decided you wanted to take part in the study. It is time for us to return to your neighborhood for the first 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. Be sure to ask any questions you may have before making your decision. We encourage you to discuss your decision with your family, friends and your doctor(s).

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to learn about changes in health over time in an urban group of 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. This is a research study where we will follow you over the next 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.



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WHAT ELSE SHOULD I KNOW ABOUT THIS RESEARCH STUDY?

It is important that you read and understand several points that apply to all who take part in our studies:

- Taking part in the study is entirely voluntary and refusal to participate will not affect any rights or benefits you normally have;
- You may or may not benefit from taking part in the study, but knowledge may be gained from your participation that may help others; and
- You may stop being in the study at any time without any penalty or losing any of the benefits you would have normally received.

The nature of the study, the benefits, risks, discomforts and other information about the study are discussed further below. The information is also explained in the informed consent booklet that goes with this consent form. 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 IS IN CHARGE OF THIS STUDY?

The research is being conducted and sponsored by the National Institute on Aging with Michele K. Evans, M.D. and Alan B. Zonderman, Ph.D. as the primary investigators. All clinical research involving human subjects is required under regulatory guidelines to be reviewed by an Institutional Review Board (IRB). An IRB performs critical oversight functions for research conducted on human subjects that are scientific, ethical, and regulatory. The NIA has hired the MedStar Health IRB to perform this service.

WHO CANNOT PARTICIPATE IN THIS STUDY?

You cannot be in this study if any of the following apply to you:

If you:

- Did not give your consent to be in the HANDLS Wave 1 study during the recruitment phase
- Do not have a valid picture ID
- Are unable to give informed consent
- Are pregnant
- Are currently undergoing cancer treatment (chemotherapy or radiation)
- Have undergone cancer treatment (chemotherapy or radiation) within the last 6 months



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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.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 3721 people will take part in this study, around 300 from your neighborhood.

WHAT HAPPENS IF I AGREE TO BE IN THE STUDY?

The HANDLS Wave 3 study data will be collected in two parts. You are required to give your consent to be able to participate in the study. The first part of the study is the examination visit to the mobile Medical Research Vehicles. The second part of the study is a telephone interview that will happen 7-10 days after your examination visit. You may also be invited to participate in a third part of HANDLS Wave 3. The third part of HANDLS Wave 3 consists of two additional studies to be conducted at Harbor Hospital and the University of Maryland. You will learn more about those studies during this examination visit, if you are eligible to participate. You will be asked to sign a separate consent form at Harbor Hospital and/or at the University of Maryland, if you decide to join either of those studies.

This is the consent form for HANDLS Wave 3. You will be asked to give your consent for all of the procedures and interviews that make up Wave 3 of HANDLS. Specifically, we want to be sure you understand the nature of 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 you may be invited to return to the MRVs to complete your testing.

For the first part you will be required to spend a day at our Mobile Medical Research Vehicles (MRVs) to have testing. You will be asked provide an update about your medical history since your last examination and you will receive a physical examination. We will ask you to remember all of the food you ate the day before your visit. We will assess your muscle strength and bone density. You will have a test to check the blood flow in your heart and to see if your heart valves are leaking. We will also ask you to complete a questionnaire and to participate in memory



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testing. You will be asked about activities of daily living, use of health care services, and any income and/or employment changes since your last visit to the MRVs. We will also take blood, tissue and urine samples.

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.

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 also be asked to give a DNA sample by using a method that collects cells from a saliva (spit) sample you provide. Before you agree to give the DNA sample you will be required to review the information below that explains the procedures and risks of providing DNA samples. More details about the specific testing for this part of the study are described below.

The tests involved in this study are described in the attached **Consent Booklet**. 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. If, after reading the **Consent Booklet**, there are tests in which you do not wish to participate, please list them on the back of this form.

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 in which vehicle it will be given.

Phase 1 – Medical Research Vehicle Examination

Measure or Procedure	Estimated Timing	Location
Consent	20 minutes	MRV2/3
Specimen Collection (Urine, Blood, DNA)	20 minutes	MRV 3
Anthropometrics (height & weight)	5 minutes	MRV 1



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Interim Medical History	20 minutes	MRV 1
Interim Physical Exam	20 minutes	MRV 1
Dietary Recall I	30 minutes	MRV 2
Cognition	40 minutes	MRV 2
Physical Performance	15 minutes	MRV 1
Echocardiogram	20 minutes	MRV 1
Questionnaires Section A	50 minutes	MRV 2
Test of Financial & Health Literacy	30 minutes	MRV 1
Body Composition/Bone Densitometry	30 minutes	MRV 1

Phase 2 – Telephone Interview

The HANDLS wave 3-telephone interview is designed to take place after your visit to our Mobile Medical Research Vehicles (MRVs). We will ask you to complete an interview over the phone. We are contacting everyone from the study to see if they would like to take part in this telephone interview. It should take about 40 minutes to complete.

The telephone interview is a dietary recall questionnaire that asks you to remember what you had to eat and drink in the last 24 hours. We will use pictures to help you give us information about how much food and drink you had in the last 24 hours. You may remember the dietary recall interview from your visit to the MRVs. The difference for this interview is that we will conduct the interview over the phone. All materials (pictures, etc.) for the phone interview will be delivered to you by US mail or given to you at the end of your MRV visit.

The telephone survey is used to collect information for our research. It is not designed to improve your health at this time. We perform the telephone survey free of charge. You may participate in telephone survey, but you do not have to. You may stop the survey after it starts. This will not affect your right to participate in the other parts of the HANDLS study. If you stop the questionnaire we will still invite you for your next MRV examination.

HOW LONG WILL I BE IN THE STUDY?

We think you will be in the study for the next 15 years because this is a longitudinal study that follows your health over time as you age. This is a study that provides long-term follow up. The study doctor or the National Institute on Aging may stop your participation in this study at any time without your consent. You can stop participating at any time. However, if you decide to stop participating in the study, we ask you to talk to the researchers first.



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WHAT ARE THE RISKS AND SIDE EFFECTS OF THIS STUDY?

If you decide to participate in this study, you should know there may be risks. The risks for this study are minimal. The descriptions of the tests given on the Mobile Medical Research Vehicles include any risks and other possible side effects. They are also explained in the **Consent Booklet** under the Assessment of Risks section. Potential risks and side effects related to this study include:

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.

This research study requires a small amount of radiation from the DEXA Scan. It must be noted that this radiation exposure is not needed for your medical care. It is for research purposes only. The total amount of radiation you will receive from this study is from one DEXA scan. The NIH Radiation Safety Committee has reviewed the use of radiation in this research study. It has approved this use as involving minimal risk and needed to obtain the research information desired.

Using the standard way of describing radiation exposure, from one DEXA Scan you will receive an effective dose of less than one thousandth of one rem. By comparison the average person in the United States receives this much radiation every day from natural sources, such as the sun. In this scan the only part of the body exposed is the skin, which is less sensitive to radiation than other parts of the body. There is a very small risk of cancer from the x-rays in DEXA scan, but is too small to measure.

If you are pregnant you may not participate in this study. Unborn babies are more sensitive to radiation than children or adults.

The risks for the dietary recall interview, the questionnaires and memory testing are very 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.



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GENETICS AND DNA TESTING

INFORMATION – WHAT HAPPENS IF I AGREE TO PARTICIPATE IN GENETICS TESTING

The purpose of this section of the consent form is to give you information regarding a blood and saliva sample requested as part of your participation in the HANDLS research study. The blood and saliva sample will be used in the genetic research described below. Genes are pieces of information that you get from each parent and are found in every cell in your body. For example, different genes are responsible for hair or eye color.

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.

PROCEDURES FOR GENETICS/DNA TESTING

You will be asked to give a DNA sample by using a method that collects cells from a saliva (spit) sample you provide. We also 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. If you decide not to participate in genetic testing, you will still be considered for the clinical research study.

WHAT ARE THE RISKS OF PROVIDING DNA SAMPLE

As part of the HANDLS study you are being asked to be in the part of the study involving genetic testing. Discomfort and inconvenience associated with participation in this part of the study come from the methods used for obtaining the blood needed to obtain the genetic sample. We expect that any discomfort you experience will be minimal. To obtain a blood sample, the needle stick may cause bruising at the site the needle goes into the skin. Fainting and, in rare cases, infection may occur. These events are easily treatable and reversible.

There are no known risks associated with the procedures used to collect the DNA (saliva) sample.

The more serious risk of genetic testing includes the possible 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



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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.

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

Please initial by the line indicating your wishes about participating in genetics/DNA testing:

___ I consent to the DNA collection

___ I do **NOT** consent to the DNA collection

WHAT WILL HAPPEN TO MY SAMPLES WHEN THE STUDY IS OVER?

The NIA will retain custody of your samples for studies as outlined above. You will retain the right to have the sample material made unavailable for future genetic testing and other specific testing by completing the section below by initialing on the line next to your choice. The NIA will be the exclusive owner of any data, discoveries or derivative materials from the sample materials and is responsible for the restriction of sample use at your request. If a potential commercial product is developed from this research project, the NIA will develop patents and promote commercialization of the product as required by law. You will not profit financially from such a product.

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

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



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Your samples will be stored in secured freezers at an NIA facility. Your name and identifying information will be removed and we will give the samples a code. The key to the code will be kept in a separate, secure area. Your samples will be used only for the study described in this consent form unless you give us permission to use them for other studies.

If a future research project arises where your samples could be useful, we ask you to designate as to whether or not your sample can be used. Any future research use will require approval by the Institutional Review Board (IRB).

Please initial by the line indicating your wishes:

___ YES, I give permission to use my (blood or other fluids, tissues) samples in future research studies under the following conditions:

___ These samples may be used for other research projects without contacting me only if the identification code is removed so that the sample can no longer be identified as mine

___ These samples may be used for other research projects without contacting me even if the code is left on the samples. I understand that if the samples are coded, they may be able to be traced back to my personally identifiable information and my medical records.

___ MAYBE, I wish to be re-contacted if further studies with my samples are considered. After the study has been explained, I will then decide if I want my samples to be included.

___ NO under no circumstances shall my samples be used for any future studies. My samples should be discarded once the present study is complete.

If you allow future research on your sample and the research provides information important for your health, we will try to contact you. If you wish to be contacted please keep the principal investigator for this study or the NIA updated about changes in your address or phone number.

HOW WILL I FIND OUT ABOUT THE GENETICS/DNA RESULTS OF THE STUDY?

The Genetics studies we do are to add to our knowledge of how genes and other factors affect the long-term health of minority and medically underserved populations. We are gathering this knowledge by studying groups of people, and the study is not meant to test your personal medical status. For these reasons, we will



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not give you the results of our research on your sample. If you have questions about whether any genetic tests would be useful to you, you should ask your doctor.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

This study is not designed to give direct benefits to any participants. If you agree to take part in this study, there may or may not be direct medical benefits to you. We hope the information learned from this study will benefit others in the future. There is no charge for any of the testing described. You may benefit by learning more about your health, or possibly from learning that you have a condition or problem. You will receive a Participant Report Package in the mail, with results of your visit to the MRVs. If the study doctor discovers any 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.

WHAT OTHER OPTIONS ARE THERE?

There are no other options associated with your participation in this study. You may choose either to participate or not to participate in this research. Taking part in this study is entirely voluntary. You may choose to withdraw from the study at any time.

WHAT ABOUT CONFIDENTIALITY?

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 records. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Privacy Act protects the confidentiality of your NIH medical record. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or authorized hospital accreditation organizations.

You will be asked to sign a separate consent form, Health Insurance Portability and Accountability Act (HIPAA), that will give permission to the investigator and sponsor (which is NIA/NIH), and certain other people, agencies or entities to look at and review the records related to this study including your personal health information (PHI)



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and the information discovered during this study. If you do not wish to sign this permission form you will not be allowed to participate in this study.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this certificate the researchers cannot be forced to disclose information that may identify you, even by court subpoena, in any federal, state, or local civil, criminal, administrative, legislative or other proceedings. The researchers will use the certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the U.S. Department of Health and Human Services that is used for auditing or program evaluation or for information that must be disclosed in order to meet federal regulations.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researcher may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following conditions: It does not apply to state requirements to report certain communicable diseases. In addition, the study doctor may be required to report certain cases of abuse, neglect, or suicidal or homicidal intent to the appropriate authorities.

If as part of this study you tell study staff that you plan to hurt yourself or someone else you should know what would happen. We will refer you for an evaluation by a mental health professional. You should also know the study doctor may have to report it to the authorities. There is a chance the authorities and the mental health professionals will find out that you are participating in this study.

DATA MANAGEMENT:

All protocols at the NIA follow the NIA Data and Safety Monitoring Plan. This includes using the Level of Risk Assessment Monitoring Guidelines that has been established for the NIA following NIH rules and regulations to ensure good clinical practices in the conduct of clinical research. Participants will be informed about new information from this or other studies that may affect their health, welfare, or willingness to stay in this study.

Data collected from the HANDLS study including Personal Health Information (PHI) is stored in the secure databases located on the *handlsdb*, *handlsmrv* and *vhandlsdev* servers. These databases are password protected and maintained on a secure NIA/NIH system with access limited to authorized NIA staff. All NIA



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staff that has access to these databases has the proper training on patient confidentiality as well as the required Human Subject Protection training.

The system is administered using the security policies and regulations required by the National Institutes of Health consistent with the Health and Human Services Privacy Rule and HIPAA. Organizations that may request inspect and/or copy research and medical records for quality assurance and data analysis include the National Institute on Aging, Office of Human Research Protection, and MedStar Health Research Institute, Institutional Review Board (IRB).

You can stop participating at any time. Any data or blood collected until that point in time would remain part of the study and the property of the National Institute on Aging. All data and blood collected is available only to authorized staff working on this protocol.

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health. Reimbursement of travel and subsistence will be offered consistent with NIH guidelines. Compensation of \$600 or more in one year will be reported to the IRS per federal regulations.

You will receive \$160 for the first phase (MRV visit) of the study. Your payment will be made in the form of an ATM debit card at the end of the MRV visit. If you are unable to complete all of the tests you may receive a portion of the payment. If you have to return to the MRVs to complete testing on another day, you could be compensated for the additional visit. The ATM card will be activated before you leave the vehicle. You will be able to take the card to an ATM machine in your neighborhood to withdraw your payment.

If you decide to participate in the second phase of this study, the follow-up telephone interview, scheduled to occur with-in 7-10 days of our MRV visit, you will be paid an additional \$40.00. Your payment will be added to the ATM debit card given to you during your MRV visit.

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.

Materials and information obtained from you in this research may be used for commercial or non-commercial purposes. It is the policy of the National Institute on Aging, National Institutes of Health and affiliated entities not to provide financial compensation to you should this occur.



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Research Institute

Consent To Participate In A
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<p>IRB Approval Stamp (ORA USE ONLY - DO NOT CHANGE ANY INFORMATION IN THIS SECTION) MedStar Research Institute APPROVAL DATE: SEP 27 2011 APPROVAL EXPIRES: SEP 26 2012 IRB APPROVED Form Revision Date: 05/10/04</p>

IRB number: 2009-149

Clinical Site Version: 08/01/2011

Project Title: Healthy Aging in Neighborhoods of Diversity Across the Life Span – Wave 3

Principal Investigator: Michele K. Evans, MD

Institution: National Institute on Aging, NIH

WHAT ARE THE COSTS?

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.

WHAT IF I'M INJURED OR BECOME ILL DURING THE STUDY?

We will make every effort to prevent injuries or illness from occurring while you are in study. In case of an injury, illness, or other harm occurring to you during or resulting directly from the study, the National Institute on Aging will provide short-term medical care for any injury resulting from your participation in research at the National Institute on Aging to the extent that such costs are not covered by your medical or hospital insurance.

You should contact the study doctor as soon as possible. The services at the National Institute on Aging will be open to you in case of any such injury. Emergency medical treatment is available, but you or your insurance will be charged for any continuing medical care or hospitalization that is provided at the usual charge by the Harbor Hospital and will not be reimbursed by the National Institute on Aging to the extent these costs are not covered by your insurance or other third party coverage.

No funds have been set aside by the National Institute on Aging, Harbor Hospital, the MedStar Health Research Institute, MedStar Health, or other affiliated entities to repay you in case of injury, illness, or other harm occurring during, or resulting from the study, and their current policies do not provide for payments for lost wages, cost of pain and suffering, or additional expenses. By agreeing to this information regarding injury or illness, you do not give up your rights to seek compensation in the courts.

WHAT CONSULTATIVE OR FINANCIAL INTERESTS ARE INVOLVED IN THIS STUDY?

The National Institutes of Health reviews NIH staff researchers at least yearly for conflicts of interest. The Following link contains details of this process <http://ethics.od.nih.gov/forms/Protocol-Review-Guide.pdf>. You may ask your research team for additional information or a copy of the Protocol Review Guide. This protocol may have investigators who are not NIH employees. Non-NIH investigators are expected to adhere to the principles of the Protocol Review Guide but are not required to report their personal financial holdings to the NIH.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

- You have the right to be told about the nature and purpose of the study;



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Principal Investigator: Michele K. Evans, MD

Institution: National Institute on Aging, NIH

- You have the right to be given an explanation of exactly what will be done in the study and given a description of potential risks, discomforts, or benefits that can reasonably be expected;
- You have the right to be informed of any appropriate alternatives to the study, including, if appropriate, any drugs or devices that might help you, along with their potential risks, discomforts and benefits;
- You have the right to ask any questions you may have about the study;
- You have the right to decide whether or not to be in the study without anyone misleading or deceiving you; and
- You have the right to receive a copy of this consent form.

By signing this form, you will not give up any legal rights you may have as a research participant. You may choose not to take part in or leave the study at any time. If you choose to not take part in or to leave the study, your regular care will not be affected and you will not lose any of the benefits you would have received normally. We will tell you about new information that may affect your health, welfare, or willingness to be in this study.

WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, contact the investigator, Michele K. Evans, MD at 410-558-8573. For medical assistance during the evening or on weekends, call the NIA Security Office at (410) 558-8119 and request that they contact the NIA Physician-on-Call.

If you are having a medical emergency, you should call 911 or go directly to the nearest emergency room.

If you are injured as a result of being in a study, or think you have not been treated fairly, please contact the NIA Clinical Director at (410) 350-3922.

For questions about your rights as a research participant, you can call or write the following:

NIA Clinical Director
3001 S. Hanover Street, 5th Floor
Baltimore, MD 21225

Telephone: (410) 350-3922
Fax: (410) 350-3979

NIA Clinical Research Protocol Office
3001 S. Hanover Street, Room 539
Baltimore, MD 21225

Telephone: (410) 350-3947
Fax: (301) 451-5576

MedStar Health Research Institute
Office of Research Integrity
6525 Belcrest Road, Suite 700
Hyattsville, MD 20782

Telephone: (301) 560-2912
Toll Free: (800) 793-7175
Fax: (301) 560-7336



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SIGNATURES

As a representative of this study, I have explained the purpose, the procedures, the possible benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

Signature of Person Obtaining Consent

Date of Signature

Print Name of Person Obtaining Consent

I, the undersigned have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to be in this study. I am free to stop being in the study at any time without need to justify my decision and if I stop being in the study I understand it will not in any way affect my future treatment or medical management. I agree to cooperate with **Dr. Michele K. Evans** and the research staff and to tell them immediately if I experience any unexpected or unusual symptoms.

Participant's Signature

Date of Signature

Print Name of Participant

Signature of Witness

Date of Signature

Print Name of Witness

As the Principal Investigator (or his designee) for this research study, I have reviewed this individual's eligibility for enrollment in the study and agree that the individual is eligible to be enrolled.

Principal Investigator's Signature

Date of Signature

Print Name of Principal Investigator



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