MedStar Health Research Institute
Informed Consent for Clinical Research

SITE: NIA Clinical Research Unit at Harbor Hospital
3001 South Hanover Street, 5th floor
Baltimore, Maryland 21225

PRINCIPAL INVESTIGATOR: **William B. Ershler, M.D.**

Co-INVESTIGATORS:

David Anderson, Ph.D.	Dimitrios Kapogiannis, M.D.	Linda Rothfield, ANP-C
Leslie Sloper, R.N., BSN	Linda Jo Byrd, B.S.	Chee Chia, M.D.
Patricia L. Duffey, RN, BSN.	Josephine Egan, M.D	Michele K. Evans, M.D.
Nazli B. McDonnell, M.D., Ph.D.	Patricia Julien-Williams, FNP-C	Alan Zonderman, Ph.D.
Luigi Ferrucci, M.D.,Ph.D.	Patricia Knighton, RN	Susan Resnick, Ph.D.
Dennis Taub, Ph.D.	Melissa Kitner Triolo, Ph.D.	Edward J. Goetzl, M.D.
Vickie Schaffner, RN	Andrew Singleton, Ph.D.	E. Jeffrey Metter, M.D.
Denise Melvin, R.N.		

INTRODUCTION

We invite you to take part in a research study called, **"Screening Protocol to Evaluate Volunteers for NIA Approved Studies**". You were selected as a possible participant in this study because you have shown interest in participating in an approved National Institute on Aging (NIA) study. Please, take your time to read this form, ask any questions you may have and make 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 National Institute on Aging is conducting a protocol to identify and evaluate volunteers who may be eligible and wish to participate in approved NIA studies. The purpose of this study is to allow you to be evaluated for IRB-approved research studies.

For every NIA research study, participants must fulfill a list of criteria, which are based primarily on their medical condition, in order to determine their suitability to participate in a research study. These eligibility criteria are necessary to ensure the integrity of the research study as well as maximize the safety for the participant in the research study. In order to determine whether you meet these eligibility criteria,

IRB Approval Stamp
(ORP USE ONLY - DO NOT CHANGE ANY INFORMATION IN THIS SECTION)

Form Revision Date: 05/10/04

we must perform a series of medical tests or procedures, such as blood tests. These tests are designed to evaluate your general medical condition and eligibility to participant in an NIA approved research study.

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. 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 William B. Ershler, M.D. as the Principal Investigator (PI).

WHO CANNOT PARTICIPATE IN THIS STUDY?

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

- You are unable to provide informed consent or, if you are a minor subject, do not have a legal guardian who is able to provide such consent on your behalf
- You do not meet the criteria of any approved NIA protocols and do not wish to remain in the contact database for future studies.
- You have contacted the NIA Clinical Research Protocol Office and notified them that you would like to be removed and no longer contacted for NIA IRB approved studies.

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 without approval from the people in charge of each 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 5,000 people will take part in this study. All subjects will be recruited at this site.

WHAT HAPPENS IF I AGREE TO BE IN THE STUDY?

We will ask you to come to the NIA Clinical Research Unit which is located on the 5th floor of Harbor Hospital, to participate in a screening evaluation. You will have the opportunity to obtain additional information about studies in which you wish to participate and discuss eligibility issues with NIA staff members. In some cases, we may ask to come to your home to conduct the screening evaluation.

The tests and procedures required for determining eligibility for the research studies are described below. You will only be asked to undergo those tests that are specific to the research study to which you are being considered. There is a possibility that you may be asked to take tests that are not listed below because the protocol you are being evaluated for requires them, at which time you will be consented on that specific protocol.

Your doctor or nurse will review the specific details of the test(s) with you. They will describe the procedure/test and the purpose of the procedure/test as well as the risks involved. If you are found to be eligible for an active study and you choose to enroll in that study and you will be contacted by an NIA staff member associated with that study.

If we find any clinical problems in need of care, we will discuss this with you. This is not a treatment study and you will be referred to your primary care physician for follow-up.

The individual going over this consent with you will check the boxes next to the standard examinations you will undergo. If additional examinations or testing are required, they will be discussed with you.

- ☐ **History and Physical Examination**: A summary of your medical record may be requested, only with your permission, from your physician at no expense to you. In addition, a physician or nurse practitioner of the NIA will review your medical history with you and will give you a physical examination, which may include standard psychological questionnaires.

- ☐ **Blood Tests**: Blood may be drawn from an arm vein or a central line, if present, if needed as part of screening. This will be used to measure your blood counts, liver and kidney function, serum

chemistries and other routine tests that determine whether you meet the requirements for participating in a specific protocol. Some studies may require virology tests. If a HIV test is performed, a separate consent will be used. Some of the blood that is drawn may also be used for research tests that may not be available in other hospital clinical labs.
The total amount of blood drawn will not exceed 120cc (approximately 8 tablespoons).

□ **Urine Tests**: Urine tests may include a routine urinalysis, pregnancy test, drug screen, or a 24-hour urine collection to measure kidney function.

□ **Electrocardiogram (EKG):** This test evaluates your heart rate and rhythm by measuring electrical impulses from the heart through electrodes that are placed on the skin. You must lie down and be still without talking during the 5 minutes the EKG is being recorded.

□ **Echocardiogram:** An echocardiogram is an ultra sound test used to evaluate the structure and function of your heart. It uses harmless high-frequency sound waves, which bounce off the heart structures as a series of echoes. The echoes are recorded on moving graph paper or a videotape.

□ **Oral Glucose Tolerance Test (OGTT):** This test will tell us how high your blood sugar levels go after you drink a standard solution of 75 grams of glucose (sugar), and OGTT is used to diagnose diabetes. You will be required to fast and take nothing by mouth except water for 12 hours starting the night before the OGTT. For the OGTT, you will be asked to drink a 10-ounce sweet orange-flavored drink. A blood sample will be taken before and 120 minutes after taking the drink. About 2 ml (2/5 teaspoon) of blood will be drawn for the OGTT test. You will be lying down on a recliner during the OGTT and will be able to get up to use the restroom as needed. At the completion of this test, you will be offered a meal ticket.

□ **Power and Strength Testing:** We will measure the force generated by your muscle groups when you exercise your arms.

□ **Lower Extremity Performance:** This evaluation includes some performance-based tests of physical function, which include timed walks, rising from a chair, maintaining a stable balance and **walking 400 meters**. During these tests you may be asked to breath in a mask connected to a portable air analyzer that estimates oxygen and energy consumption during these activities.

STORED SAMPLES AND FUTURE STUDIES

We are also asking your permission to collect and store biological fluid (blood, urine, etc.) from you during the screening process. These samples will be left over from tests or procedures that are necessary to determine your eligibility. Your stored samples will be kept in a research laboratory at the National

Institute on Aging. Your samples may be tested immediately, or they may be frozen and used later. All samples will be stored with a confidential code and may be kept until no cells remain or until the investigators decide to destroy them. Your sample may be used to test out new laboratory procedures or used to develop and test laboratory methods of measuring and analyzing genes, The results from the research done with your stored samples are experimental and since they are coded, will not be given to you or your private physician nor will results be put in your medical record.

In the future, other investigators (at NIH or outside NIH) may wish to study your stored sample. When the study team shares your materials, they may share it with the coded label only so that the sample cannot be linked to you. Some information about you, such as gender, age, health history, or ethnicity may also be shared with other investigators in the same coded way. Any current or future research studies using your samples will be reviewed by NIA's Institutional Review Board (IRB), a special committee that overseas medical research studies to protect the rights and welfare of human subject volunteers. In addition, an NIA internal review, including the Principal Investigator, will be required to insure the scientifically appropriate use of all samples obtained from this protocol. The stored material will be used only for research and will not be sold. The research done with the subject's materials may be used to developed new products in the future but the subject will not receive payment for such products.

If you decide now that your samples can be kept for research, you can change your mind at any time. Just contact us and let us know that you do not want us to use your samples. Then any sample that remains will be destroyed. Please read each sentence below and think about your choice. After reading each sentence, circle and initial the answer that is right for you. No matter what you decide to do, it will not affect your participation in other NIH studies or your care.

Yes No Initials _____ My samples may be kept and used by the NIA for research purposes.

HOW LONG WILL I BE IN THE STUDY?

This is a screening protocol. Your time spent will be only to evaluate you for possible participation in NIA approved studies. Testing should be one day. However, should a test be inconclusive you may be asked to come back to repeat the test or to take a test you did not take the first time.

You may be re-evaluated within a year for potential participation in future studies should you decide to remain on this study and part of our research database, if you decide you would like to remain on our research database.

Your participation in this study may be stopped at any time by the study doctor or the National Institute on Aging without your consent if:

- The study physician thinks it necessary for your health and safety
- You have not followed the study instructions

IRB Approval Stamp
(ORP USE ONLY - DO NOT CHANGE ANY INFORMATION IN THIS SECTION)

Form Revision Date: 05/10/04

- The National Institute on Aging has stopped the study; or
- Administrative reasons require your withdrawal

Any data or blood collected until that point in time would remain part of the study.

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

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. You should discuss these with the investigator and/or your regular doctor and you are encouraged to speak with your family and friends about any potential risks before making a decision. Potential risks and side effects related to this study include:

All the tests and procedures included in this screening protocol are routine. Like some medical tests, there are some associated risks and discomforts. The following describes the most common risks of these tests and procedures. Your physician or nurse will also discuss with you in detail any risks or discomforts of the procedures or tests you will be scheduled to undergo.

- **Blood tests:** Drawing blood from your arm may cause pain, bruising at the site of the needle puncture, lightheadedness, and, on rare occasions, infection and fainting. If a bruise does form at the end of the needle puncture site, it will generally go away on its own without any treatment. If you have a central line, drawing blood from this line is associated with a small chance of infection that may be treated with antibiotics, or rarely, removal of the line. There is also a small chance of blood clot, air in the catheter or a break or cut in the line. If repairs are not possible, the line may have to be removed.

- **EKG and Echocardiogram**: These procedures are associated with minimal risk and minimal discomfort. There is a small chance of rash from electrodes placed on the skin.

- **Blood and Urine Samples**: Specimens may be collected from you during the screening process and saved for the NIA research study for which you are being evaluated. Should you not qualify for any NIA studies, your specimen will be destroyed. If there are any risks to you or your family associated with these scientific studies, which are not covered in this consent form, a separate consent will be obtained before such studies are performed.

- **Risks of Oral Glucose Tolerance Test**: Besides possible bruising from the needle from the blood draw, drinking the sugar solution may lead to a temporary sense of abdominal fullness and discomfort, nausea, vomiting, or diarrhea, but it is a rare occurrence.

- **Risks of 400 Meter Walk and Lower Extremity Performance:** In rare cases these exertions can lead to chest pain, shortness of breath, irregular heartbeats, and dizziness. In most cases, these symptoms disappear after a few minutes of resting. During the tests that involve walking there is some risk of falling, which is similar to the risk of falling while performing many activities of daily living. There may be a slight, transitory irritation of the skin from wearing the breathing mask.

For more information about risks and side effects, ask the researcher William B. Ershler, M.D., or contact the NIA Clinical Research Protocol Office at 410-350-3947.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

You may experience direct benefit from participation if you have a previously undiagnosed condition that is diagnosed, if you are informed of alternative treatment or options, or if you are enrolled into another study.

Any clinical results that may come from the screening tests and procedures that you do participate in will be provided to you with an additional copy for your personal physician, if you so desire.

WHAT OTHER OPTIONS ARE THERE?

This study does not provide treatment and does not replace tests or care that you receive from your primary care physician. The alternative to participating in this study is not to participate. Taking part in this study is entirely voluntary.

WHAT ABOUT CONFIDENTIALITY?

Your personal health information (PHI) will be kept private to the extent allowed by law. You will not be identified by name in any publications resulting from this study. You will be asked to sign a separate form that will give permission to the investigator, the sponsor, and certain other people, agencies or entities to look at and review the records related to this study including your personal health information 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.

Organizations that may request, inspect, and/or copy your research and medical records for quality assurance and data analysis include groups such as: the National Institute on Aging, Food and Drug Administration, Office of Human Research Protection, MedStar Health Research Institute, Institutional Review Board (IRB).

A Data Safety and Monitoring Board, which is a group of experts not connected to the study, may be reviewing the data from this research throughout the study. We will tell you about the new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

Records will be kept using Clinical Management Software products called Study Manager and Oracle Clinical Applications. These softwares are HIPAA (Health Insurance Portability and Accountability Act) compliant software developed by Advanced Clinical Software and Oracle Corporation respectively. These databases are password protected and maintained on a secure NIA/NIH internet with access limited to authorized NIA staff members. All NIA members who have access to these databases have the proper training on patient confidentiality as well as the required Human Subject Protection Training.

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

You will not be paid for being in this study. Materials and information obtained from you in this research may be used for commercial or non-commercial purposes. It is the policy of NIA, Harbor Hospital, MedStar Health Research Institute, MedStar Health, Inc. and its affiliated entities not to provide financial compensation to you should this occur.

Not all tests are required for your screening visit. However, if you are required to do an OGTT test, which require you to fast for 12 hours prior to your visit, we may provide you with a meal ticket.

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 and illness from being in the study. If you have any adverse experience 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 here to the extent that such costs are not covered by your medical or hospital insurance.

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 will be provided at the usual charge by the Harbor Hospital.

You should not expect anyone to pay you for your pain, worry, lost of income or non-medical care costs that occur from taking part in this study. No long term medical care or financial compensation for research related injuries will be provided by the National Institutes of Health, the Federal Government, Harbor Hospital, MedStar Health Research Institute or MedStar Health.

You or your insurance company will be charged for continuing medical care and/or hospitalization that are not apart of the study. By agreeing to this you do not give up your rights to seek compensation in the courts.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

- You have the right to be told about the nature and purpose of the study;
- You have the right to be given an explanation of the 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, William B. Ershler, M.D. at 410-350-3922. 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 or Deputy 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
Phone (410) 350-3922

NIA Clinical Research Protocol Office
3001 S. Hanover Street, Room 539
Baltimore, MD 21225
Phone: (410) 350-3947
Fax: (410) 350-3979.

MedStar Health Research Institute
Office of Research Integrity
6525 Belcrest Rd, Suite 700
Hyattsville, MD 20782
Phone: (301) 560-7339
Toll Free: (800) 793-7175
Fax: (301) 560-7336

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

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 William B. Ershler, M.D. and the research staff and to tell them immediately if I experience any unexpected or unusual symptoms.

Participant's Signature	Date of Signature
Signature of Witness	Date of Signature
Signature of Legally Authorized Representative (When Appropriate)	Date of Signature
Relationship to Participant (When Appropriate)	Date of Signature

IRB Approval Stamp
(ORP USE ONLY - DO NOT CHANGE ANY INFORMATION IN THIS SECTION)

Form Revision Date: 05/10/04