1. OVERVIEW OF THE RESEARCH STUDY:

We are asking you to be in a research study that is being supported by the VA Office of Rehabilitation Research and Development. Before you decide to take part, you should know why the study is being done and what it will involve. This form tells you what to expect if you agree to be in the study. Taking part in this study is completely voluntary; it is your decision whether or not to participate in the study.

We are doing the research to assess the feasibility of exercise programs to improve memory. If you agree, you will complete some memory tests and questionnaires and participate in one of two home-based programs. You will be in the study for 6 months if you decide to stay for the whole study. We will describe your involvement in more detail later in this form.

You might choose to volunteer in the study because exercise might potentially improve your memory, physical fitness, and quality of life. You will find more information about benefits later in this form.

You may choose not to volunteer to be in the study because of the possibility that you may experience discomfort during normal exercise. You will find more information about risks later in this form.

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

2. WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this research study is to compare two approaches to providing a home-based exercise program to people with mild cognitive impairment. We are asking you and approximately 60 other veterans to participate in this study. This study is supported by the Department of Veterans Affairs.

3. HOW LONG WILL I BE IN THE STUDY? WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

You will be allowed to participate as long as your physician has no objections to your participation. You will be asked to complete two evaluations over a 6-month period (at baseline and 6 months) at the Jamaica Plain campus of the VA Boston Healthcare System. At the first visit (baseline), you will be asked some questions about your memory and physical activity. We will also draw 8 cc (one and a half teaspoons) of blood at your visit to analyze the hormone insulin-like growth factor-1 and the genetic marker apolipoprotein Eε4. This visit will take approximately 2 to 2½ hours.

If you meet all eligibility criteria, you subsequently will be randomly assigned – that is, by chance – to one of two groups. Both groups will use a special telecommunications system 3 times per week at home to complete all sessions. If assigned to the first group, you will be asked to carry out a structured exercise program using various weights for 6 months. A typical session will last about one hour. If

assigned to the second group, you will be taught a lifestyle exercise program using a telecommunications system in which you will hear about similar exercises and, in addition, will be advised about general health topics for 6 months. A typical session will last about 15 minutes. You will be shipped at no cost to you all study materials and equipment. During your 6 months of participation, we will call you every 2 weeks to check on how you are doing.

At 6 months you will be asked to repeat the memory tests and provide another blood sample for analysis of the hormone insulin-like growth factor-1. This second visit will take approximately 1 to 1½ hours. When your participation is complete, you will be asked to ship all study equipment back to us at no cost to you.

4. WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Discomfort or inconvenience involved in this study are those associated with normal mild exercise. You may experience fatigue as your muscles tire or ache during or immediately after exercising. You may also find the needlestick to draw blood to be uncomfortable or unpleasant.

Reasonably foreseeable risks include bruising or bleeding at the site where the blood is drawn. Rarely, fainting occurs as a result of drawing blood. The risks associated with training include strained and pulled muscles, rapid heart beat, labored breathing, chest discomfort, light-headedness, dizziness and falls. If you experience any of these symptoms, you should stop exercising and contact your physician as well as study staff. Also, in addition to the risks listed above, you may experience a previously unknown risk or side effect.

5. WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no known direct benefits to you for being in this study.

6. DO I HAVE TO TAKE PART IN THE STUDY?

Your participation in this study is voluntary. If you refuse to take part, you will not suffer any penalty or loss of benefits to which you are otherwise entitled.

You may withdraw from the study at any time. This will end your participation in the study, however, the research team may continue to use the data and blood specimens that have been already collected before your withdrawal. You will be asked to ship all study equipment back to us at no cost to you.

7. WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

The only alternative to participate is to choose not to participate.

8. RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

Your participation in the study can be terminated by the study Principal Investigator if it is determined that it is not safe for you to continue in the study. If terminated, you will ship all study equipment back to us at no cost to you.

9. HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Information collected for the purpose of this research study will be kept confidential as required by law. The results of this study may be published for scientific purposes, but your records or identity will not be revealed unless required by law.

Information about you is protected in the following way: We will store your information in ways we think are secure. To protect confidentiality, data will be identified only by study ID number assigned to you. All computer files will be secured using access permissions and assigned passwords to ensure only authorized study personnel will have access to your data. Access permissions and passwords will be changed whenever there has been a change in study personnel. Any required personal information on you will be kept in a separate file and only the Principal Investigator and Study Coordinator will have access permissions granted to this file. All of your paper forms will be secured in a locked fireproof study cabinet. Only the Principal Investigator will have keys to the study cabinet.

Your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

We will store blood samples taken from you at the MAVERIC Core Laboratory located at Jamaica Plain campus of the VA Boston Healthcare System.

While this study is being conducted, you will not have access to your research related health records. This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care.

Your research records will be kept indefinitely or until the law allows their destruction per the VA Record Control Schedule (www1.va.gov/VHAPUBLICATIONS/RCS10/rcs10-1.pdf). Records will be destroyed, when allowed, in the following manner

- Paper records will be shredded
- Electronic records will be destroyed in a manner in which they cannot be retrieved.
- Blood samples will be discarded one year after the end of the study with biological laboratory waste for pick-up and disposal by VABHS Environmental Management Service.

Your research records and the information within them will not be used for any purpose other than that described in this study as approved by the IRB.

Genetic testing and/or collection of genetic information
There are state and federal laws that protect against genetic discrimination. There is a federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most employers (those with 15 or more employees) to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Health Information Portability and Accountability Act (HIPAA)
There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as your medical history.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the Institutional Review Board, Research & Development Committee, Research Compliance Officers, Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO).

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, **Dr. David Sparrow** and his research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

An unsigned copy of this consent form will be posted on clinicaltrials.gov or Regulations.gov after all study participants have completed the study.

10. WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

You will be told of any significant new findings that come to light during the course of this study and that may relate to your wanting to stay in the study.

11. WHAT ARE THE COST TO ME IF I TAKE PART IN THIS STUDY?

A participant will not be required to pay for medical care and services received as a participant in an approved VA research study. Some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services (including, but not limited to, dental services, supplies, medicines, orthopedic and prosthetic appliances, and domiciliary or nursing home care) provided by the VA that are not part of this research study.

12. WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

In the event that you are injured as a result of your being in this research study, you will receive medical care, including emergency treatment. This care or treatment is governed by federal law and VA policy. You would also have the right to file any legal action, as in any instance of alleged negligence.

14. WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

I understand that if I have any medical questions about this research study, I can call **Dr. Pantel Vokonas** (Medical Director of the VA Normative Aging Study) at (857) 364-6400 during normal working hours.

I understand that if I have any general questions about this research study, I can call **Dr. David Sparrow** at (857) 364-6400 during normal working hours.

I understand that if I have any medical problems that might be related to this study that **during the day** I can call **Dr. Pantel Vokonas at** (857) 364-6400 and **after hours** I can call toll free 1-877-204-5849 and ask the answering service to call or page the person on call for the Normative Aging Study.

I understand that, if at any point during or after this study I have any questions about my rights as a research participant or I want to discuss problems, complaints, concerns, and questions about the research, obtain information, or offer input, I may contact the Research Compliance Officer at (857) 364-4182.

15. AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

I have read or have had read to me all of the above. Study staff have explained the study to me and answered all of my questions. I have been told of the discomforts and risks of the study. I have been told of other choices of treatment that I could have.

I understand that my participation in this study is voluntary, that I do not have to take part in this study and that, if I do take part, I may withdraw from the study at any time. I also understand that, if I refuse to take part or if I decide to withdraw, I will not suffer any penalty, loss of rights, or loss of VA or other benefits that I have a right to receive.

I voluntarily consent to be in this study. I will receive a signed copy of this consent form.

Participant's Signature **Month Day Year** **Name (print)**