Department of Veterans Affairs	**INFORMED CONSENT FORM**
	Date:
Title of Study: Preventing Loss of Independence through Exercise (PLIÉ) in Persons with Mild Cognitive Impairment (MCI)	
Principal Investigator: Linda Chao, PhD	**San Francisco VAMC**

What is the name of this research study?

- Preventing Loss of Independence through Exercise (PLIÉ) in Persons with Mild Cognitive Impairment (MCI).

Who is the Principal Investigator?

- Linda L. Chao, PhD

Who is paying for this study?

- The Department of Defense
- Drs. Barnes, Chesney and Mehling are co-inventors of PLIÉ, and the University of California and the Department of Veterans Affairs jointly own the rights to PLIÉ. They may benefit financially if the program is commercialized.

Why is this research study being done?

- To find out whether a new gentle group movement program called **Preventing Loss of Independence through Exercise (PLIÉ)** can improve brain function and quality of life in people with mild cognitive impairment (MCI).
- A description of this clinical trial 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.

Why am I being asked to take part in this research study?

- You are a veteran and/or are willing to attend PLIÉ classes at the study site two times per week for 12 weeks as part of this study.

What will happen if I take part in this study?

If you agree, the following things will happen:

- I will describe the study to you and you will decide whether or not you want to participate. Then I will give you a short test of your memory and thinking. This will take about 60 minutes.
- Depending on your memory test score, I may ask for your permission to talk with the person who knows you best (Such as your spouse or a person who lives with you) about your daily activities.
- Before you begin the PLIÉ program, you will have a brain scan called a MRI. During the brain scan, you will lie on a narrow bed and be placed inside a tunnel-shaped magnet (that is 6 feet long by 22 inches wide and open at each end). You will be asked to lie quietly and as still as possible. During the scan there will be a series of loud

knocking/banging noises or a machine-type noise that is made by brain scanning machine. The scan will last for approximately 60 minutes.

- Also, before you begin the PLIÉ program, you will take some tests of your physical functioning. These including standing with your feet together side-by-side, with one foot in front of the other, and with the side of heel of one foot touching the big toe of the other foot, walking for a short distance at your usual speed, and standing up from a chair without using your arms
- You will also take some tests of cognitive functioning (such as memory), and you will answer some questions about your feelings and quality of life.
- The physical and cognitive function tests and quality of life questionnaires will take approximately 60 minutes to complete.
- You may have an optional test of your oculomotor function. This involves sitting in a chair with a head and chin rest for stability and following a moving dot on a computer screen with your eyes. The test will take approximately 3 minutes to complete.
- The PLIÉ instructor will call you before the classes start and ask you some questions about your background, interests and goals.
- You will participate in the PLIÉ program for 60 minutes, 2 days per week for 12 weeks.
- The MRI brain scan, tests of your physical and cognitive function and questions about your feelings and quality of life will be repeated after approximately 3 months. The questions and tests will take about 60 minutes, and the MRI brain scan will take an additional 60 minutes. The tests and MRI brain scan will not need to be scheduled for the same day.
- The PLIÉ instructor will call you once a month to see if there have been any changes in your health status, medications or daily routine.
- Your thoughts and feelings about the program may be written down so that we can make it better. We also may write down some of our observations about how the program is affecting you.
- Everyone must consent to the video-recording for quality control and training purposes. You will have the option to allow for (1) private viewing only – viewing limited to the research team, auditors, and monitoring committee, or (2) private and public viewing – viewing available to the public as videos in the training manual, shown at research or educational meetings, and/or posted on the study website.

Are any of the procedures experimental?

 The PLIÉ program is experimental.

How long will I be in this research study?

- You will be in this study for a total of 30 hours over 4 months. See breakdown below:

Consent	1 hour
Baseline assessment	1 hour
Baseline MRI	1 hour
PLIÉ program	1 hour, 2 days a week for 12 weeks: 24 hours
Check-in calls	20 minutes, monthly for 3 months: 1 hour
3-month assessment	1 hour
3-month MRI	1 hour

What are the risks or discomforts?

- Some of the questions or tests may be stressful, unpleasant or difficult.

- You may experience muscle strain, soreness, muscle cramps, falls or other discomfort or injury caused by the exercises. Exercise is not recommended in people with certain heart, lung or joint conditions.
- Your eyes may become dry during the computer oculomotor test.
- You may experience a loss of privacy if information is released to individuals outside the research team.
- You may find the video-recorded sessions of the study uncomfortable or stressful.
- Because the MRI machine acts like a large magnet, it can move iron-containing objects into the scanner room during your examination, which may possibly harm you. However, precautions will be taken to prevent this from happening: loose metal objects, such as coins, jewelry, pocketknives or key chains are not allowed in the scanner room; if you have a piece of metal in your body, such as a fragment in your eye, aneurysm clips, ear implants, spinal nerve stimulators or a pacemaker, you may not be allowed in the scanner room and have a MRI. One potential hazard of the MR scanner using low energy radio waves to take pictures of the brain is heating of the body. However, the machine has safety devices that prevent this from happening. There is also a possibility that during some of the procedure you may temporarily experience slight tingling in your arms, legs, feet or hands. While there
  are safety devices that prevent this from happening on a regular basis, this can occur in rare cases. To reduce this risk, you will be asked to avoid skin-to-skin contact between your extremities, such as clasping your bare hands or crossing your bare feet. In any case, such sensation is temporary and harmless.
- Having an MRI may be uncomfortable. In particular, you may be bothered by feelings of claustrophobia and by the loud banging noise during the study. Temporary hearing loss has been reported from this loud noise. This is why we will give you ear plugs and headphones to wear. During the MRI, you will be asked to lie as still as possible, which can also be uncomfortable.
- Participation in this research study may involve risks that are not foreseeable.

What are the benefits?

- Some people in the study may experience improvement in their physical function (such as balance), cognitive function (such as memory), or feelings about their life, but this is NOT guaranteed.
- You will be helping to answer an important research question. Information from the study may help health professionals better understand what types of exercises are most beneficial for people with memory loss.

What other choices do I have if I do not take part in this study?

- You can decide not to participate in any or all parts of the study.
- You can ask your doctor to suggest other exercise programs or engage in exercise on your own at home.
- You can choose not to take part in classes that are being video-recorded.
- If you decide not to take part in any or all parts of this study, you will not be penalized in any way. You can keep participating in activities the way you usually do.

How many people will take part in this study?

- 40 people with mild cognitive impairment (MCI) will take part in this study.

Where will this study take place?

- Study procedures will occur at the San Francisco VA Health Care System
- Study classes may occur at SFVA or other local facility such as the YMCA.

Will information about me be kept private?

- We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy.
- Data collected for this study may be stored in electronic research databases at the San Francisco VA or the UCSF Medical Center.
- We are legally and ethically required to report certain events to appropriate authorities such as thoughts of suicide or homicide, or suspicions of abuse.
- If we notice any abnormalities on your MRI scan, we will notify you by phone and ask for your permission to notify your doctor.
- Your personal or medical information may be shared with medical personnel if you are injured during the study or if there is concern about your well-being.
- Your personal information may be seen or copied by people who are checking to make sure we are doing a good job, including UCSF's Committee on Human Research, San Francisco VA Research & Development Committee, representatives of the Department of Defense, or other study auditors.
- A medical record may be created at the San Francisco VA Medical Center because of your participation in this study. Your consent form and some of your research records may be included in the medical record. Therefore, if you are a VA patient, your healthcare providers may become aware of your participation in this study. All healthcare providers are required to treat information in medical records confidentially.
- If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.
- People outside of the research team may view the videos for research and educational purposes. If you agree, we also may release some videos publicly (e.g., study website).

What happens if I am injured while taking part in this study?

- If you incur an injury or illness as a result of being in this study, the Department of Veterans Affairs (VA) will ensure that treatment is made available at a VA medical facility or non-VA facility, as appropriate. If you were following study instructions, the costs of such treatment will be covered by the VA. If you were NOT following study instructions, the costs of such treatment may be covered by the VA or may be billed to you or your insurer just like any other medical costs, depending on a number of factors. The VA does not normally provide any other form of compensation for injury or illness. For further information about this, call the VA District Counsel at (415) 750-2288.

Can I stop being in the study?

- Yes, you can stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study.
- Also, we may ask you to stop taking part in this study if we feel it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What will happen if I stop being in the study?

- If you decide to stop being in the study, you will go back to your usual activities.

Are there any costs to taking part in this study?

- No, you will not be charged for any of the study treatments or procedures.

Will I be paid for taking part in this study?

- We will pay you $50 by check after you finish each brain scan. You can expect to receive the check immediately upon completing the brain scan.

What will happen if there is any new information that might affect my willingness to participate in this study?

- If we become aware of any important new findings, we will contact you as soon as possible.

What are my rights if I take part in this study?

- Taking part in this study is completely your choice.
- You may choose either to take part in the study or not take part in the study. If you decide to take part in the study, you may leave the study at any time, for any reason.
- No matter what you choose, you will not be penalized in any way. You will not lose any of your regular benefits, and you can still get your care the way you usually do.

What will happen to my information once the study is over?

- We will store information collected about you in this study in accordance with the Veterans Health Administration Records Control Schedule (VHA RCS) 10-1.
- Other researchers may request permission to use data from this study to answer other research questions; however, your personally identifying information (such as your name or contact information) will not be shared.

Will I be told the results of the study?

- Yes, at the end of the study, we will let all study participants know the overall results of the study.
- You will not be given your personal results.

Who can answer my questions about the study?

- You can talk to the researchers about any questions, concerns or complaints you may have about this study. Dr. Linda Chao, the Principal Investigator, may be contacted at 415-221-4810 ext. 24386.
- If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Office of the Committee on Human Research at UCSF, which is a group of people who review the research to protect your rights.
    - Phone: 415-476-1814, 8 am to 5 pm, Monday through Friday.
    - Address: Committee on Human Research, Box 0962 University of California, San Francisco (UCSF) San Francisco, CA, 94143

CONSENT:

- You have been given a copy of this consent form to keep.
- You have been given the *Experimental Subjects Bill of Rights*.
- You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about yourself.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, please sign below.

Date	Primary Participant's Signature for Consent
Date	Person Obtaining Consent

CONSENT FOR OCULOMOTOR TESTING

I agree to undergo the test of my oculomotor function, which involves sitting in a chair with a head and chin rest for stability and following a moving dot on a computer screen with my eyes. I understand that the test will take approximately 3 minutes to complete.

Date	Participant's Signature for Consent
Date	Person Obtaining Consent

CONSENT FOR VIDEO RECORDING

Some of the classes and assessments may be recorded for research and educational purposes. Please check below if you want these videos to be available for PRIVATE VIEWING ONLY (i.e., research/education only) or for PUBLIC AND PRIVATE VIEWING (e.g., study website).

☐ I AGREE to be in the video-recorded sessions of the study for PRIVATE VIEWING ONLY (i.e., research/education only).

☐ I AGREE to be in the video-recorded sessions of the study for PUBLIC AND PRIVATE VIEWING (e.g., study website).

_____ _____

Date Primary Participant's Signature for Consent

_____ _____

Date Person Obtaining Consent

CONSENT FOR FUTURE CONTACT

We would like to contact you in the future to follow up and/or to tell you about other studies. However, you have the option to opt out if you do not want to be contacted. Check the appropriate box below.

☐ I DO NOT AGREE to be contacted in the future.

☐ I AGREE to be contacted in the future about THIS RESEARCH STUDY ONLY.

☐ I AGREE to be contacted in the future about THIS RESEARCH STUDY AND OTHER RESEARCH STUDIES.

If you are willing to be contacted, please sign below.

_____ _____

Date Participant's Signature for Consent

_____ _____

Date Person Obtaining Consent

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject, I have the following rights:

1. To be told what the study is trying to find out,
2. To be told what will happen to me and whether any of the procedures, drugs, or devices is different from what would be used in standard practice,
3. To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me for research purposes,
4. To be told if I can expect any benefit from participating, and, if so, what the benefit might be,
5. To be told of the other choices I have and how they may be better or worse than being in the study,
6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study,
7. To be told what sort of medical treatment is available if any complications arise,
8. To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my right to receive the care I would receive if I were not in the study,
9. To receive a copy of the signed and dated consent form,
10. To be free of pressure when considering whether I wish to agree to be in the study.

If I have other questions I should ask the researcher or the research assistant. In addition, I may contact the Committee on Human Research, which is concerned with protection of volunteers in research projects. I may reach the committee office by calling: (415) 476-1814 from 8:00 AM to 5:00 PM, Monday to Friday, or by writing to the Committee on Human Research, Box 0962, University of California, San Francisco, CA 94143.

Call (415) 476-1814 for information on translations