ALBERT EINSTEIN COLLEGE OF MEDICINE

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called **Motor Imagery: A Pilot Intervention for Improving Gait and Cognition in the Elderly.** Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits

The researcher in charge of this project is called the "Principal Investigator." Her name is **Dr. Helena Blumen**. You can reach Dr. Blumen at:
Office Address:
1225 Morris Park Avenue, # 313 B
Bronx, NY 10461
Telephone: 718 430 3810

For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253 or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg #1002
Bronx, New York 10461

Support for this research study is provided by the **National Institute of Health**

Why is this study being done?

The goal of this study is to evaluate whether walking and cognitive (learning, understanding and remembering) difficulties among senior citizens is a potentially preventable condition rather than an irreversible consequence of aging and disease. This study aims to determine if seniors show improved mobility (the ability to walk or move freely and easily) and/or cognition following imagery (visualization) training.

This study compares two interventions, both include imagery. One group will participate in motor imagery (visualizing themselves walking). The other group will participate in visual imagery (visualizing an octopus)

This study will provide important information regarding the usefulness of imagery interventions to prevent walking and cognitive disabilities. Contrasting motor imagery with visual imagery allow us to determine the relative usefulness of these forms of imagery for preventing walking and cognitive disabilities.

Why am I being asked to participate?

You are being asked to participate in this study because you are 65-85 years old and have responded to recruitment fliers posted around Albert Einstein College of Medicine, Montefiore University Hospital, internet sites, or have been contacted via market mailing to a Bronx and Westchester County Registered Voter List. A total of 58 participants will be enrolled in this study.

What will happen if I participate in the study?

If you agree to participate in this study you will be randomly assigned into either a 12-week telephone-based motor imagery intervention or a 12-week telephone-based visual imagery intervention. Both interventions consist of **3 (15-minute) phone calls per week for 12 weeks**. Total training time is 45 minutes per week. In one group, the training will consist of motor imagery specifically design to improve attention and mobility. In the second group, the training will consist of visual imagery. If you agree to participate in this study, you will be invited to **two study visits** (one before and one after the 12-week intervention)**.** During these study visits, the study interviewer will ask you questions about your medical history, education, daily activities and occupation. You will receive test of cognitive functions such as memory and attention. You will also receive neurological and mobility evaluations of gait (the way you walk), balance, coordination, vision, sensation and the strength and tone of muscles. **Each study visit will last for 2.5-4 hours. If needed, testing can be completed during an additional visit.**

During the two study visit you will also undergo **Magnetic Resonance Imaging (MRI)**. MRI permits us to examine how the brain responds to our interventions. MRI is a test that uses magnets and radio waves to make pictures of organs and structures inside the body. For an MRI test, the area of the body being studied is placed inside a special machine that contains a strong magnet. Pictures from an MRI scan are saved and stored on a computer for more study. Although the MRI you will have in this study is being done for research purposes only, it is possible that doctors may notice something that could be important to your health. If so, we will contact you to explain what was seen and tell you whether you should consult your doctor. We will make the MRI report available to your doctor, and if you want, we will talk with your private physician or refer you to someone for follow-up.

During one of the two study visits, you also have the choice to provide a blood sample for genetic testing. To obtain the blood sample, we will wipe the skin on your arm with alcohol to clean it. Then, we will insert a small needle into a vein. Five tubes of blood will be drawn, which comes out to about 4 tablespoons.

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.

How many people will take part in the research study?

You will be one of 58 people who will be participating in this study.

Will there be audio and/or video recording?

Your auditory responses will be recorded during some evaluations and used only to determine the timing and accuracy of your responses. Only the principal investigator and her research

team will have access to your recording. Your auditory recording will be given a code number and separated from your name. Your auditory recording will be kept as long as they are useful for this research.

Genetic Testing

Genes are made up of DNA, and have the information needed to build and operate the human body. Your blood will be tested for genetic changes that may relate to the usefulness of imagery interventions in you or your offspring. **DNA will be extracted from your blood sample, if you chose to provide one.** The information obtained from these tests will include genetic information about you. To protect your identity, we will give your specimen(s) a code number. Genetic factors are inherited and run in families. Since genetic information is shared by family members, the information from these tests may apply to your family members, as well.

Information Banking (Future Use and Storage)

We will store information about you in a "bank", which is a library of information from many studies. This information cannot be linked to you. In the future, researchers can apply for permission to use the information for new studies to prevent, diagnose, or treat disease. Your information may be kept for a long time, perhaps longer than 50 years. If you agree to the future use, some of your de-identified health information (not linked to you) may be placed into one or more scientific databases. These may include databases maintained by the federal government.

You can choose not to participate in the bank and still be part of the main study

INITIAL ONE (1) OF THE FOLLOWING OPTIONS

_____ I consent to have my information used for future research studies.

_____ I do NOT consent to have my information used for future research studies. The information will be destroyed at the end of the study.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your information or for any tests, treatments, products or other things of value that may result from the research.

If you chose to provide a blood sample, we will also store your specimens and information about you in a "biobank", which is a library of information and specimens (tissue and blood) from many studies. These specimens and information can be linked to you. In the future, researchers can apply for permission to use the specimens and information for new studies to prevent, diagnose or treat disease, including genetic research. If you agree to the future use, some of your de-identified genetic and health information (not linked to you) may be placed into one or more scientific databases. These may include databases maintained by the federal government. Your specimens and information may be kept for a long time, perhaps longer than 50 years. You may remove your consent for future research at any time by contacting the Principal Investigator named on the first page of the consent or the IRB office at 718-430-2237. If you do, we will destroy remaining specimens and information but if these were already shared with other researchers, we cannot get them back.

You can choose not to participate in the biobank and still be part of the main study and this will not affect your treatment at this facility**.**

INITIAL ONE (1) OF THE FOLLOWING OPTIONS

_____ I consent to have my specimens and information about me used for future research studies.
_____ I do NOT consent to have my specimens and information about me used for future research studies. Information about me will be kept as long as required by regulations and institutional policy, but will not be used for future studies.

_____ I do NOT consent to have my specimens collected for this research study.

INITIAL YOUR CHOICE BELOW

_____ I consent to be contacted in the future to learn about:
_____ New research protocols that I may wish to join.
_____ General information about research findings.
_____ I do not want to be contacted at all.

Will I be paid for being in this research study?

You will receive **$50 for the first study visit, $25 for the phone-based intervention, and $ 50 for the second study visit, for a total of $125** for the study. We will also provide **free transportation** to and from each study visit. If you choose to withdraw from the study before all study visits or the phone-based intervention are completed, you will be paid only for the parts you completed.

Will it cost me anything to participate in this study?

There will be no cost to you to participate in the study.

Are there any risks to me?

- You may be embarrassed if you have some difficulties with some of the cognitive and or motor evaluations that you will be asked to perform.
- Some people may experience mild temporary distress after taking cognitive evaluations. If any distress is experienced, you will have the opportunity to have your questions answered by the investigators.

Blood Draw

- Rarely, the vein where we inserted the needle will become sore or red. Sometimes, a temporary harmless “black and blue” may develop. Very rarely, fainting may occur.

Confidentiality

We will keep your information confidential. Your research records will be kept confidential and your name will not be used in any written or verbal reports. Your information will be given a code number and separated from your name or any other information that could identify you. The form that links your name to the code number will be kept in a locked file cabinet and only the investigator and study staff will have access to the file. All information will be kept in a secure

manner and computer records will be password protected. Your study information will be kept as long as they are useful for this research.

Medical information collected during the research, such as test results, may be entered into your Montefiore electronic medical record and will be available to clinicians and other staff at Montefiore who provide care to you.

The only people who can see your research records are:

- the research team and staff who work with them
- the organization that funded the research: The National Institute of Health
- groups that review research (the Einstein IRB, and the Office for Human Research Protections)

These people who receive your health information, may not be required by privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them. All of these groups have been asked to keep your information confidential.

Certificate of Confidentiality

As a way to protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health, which is funding this study. If information from this study was requested or subpoenaed by government agencies or the courts, we will use the Certificate to attempt to legally refuse to provide it. This is rare – in only a few cases did researchers have to use the Certificate, and it was honored most of the time, but not every time. There are several kinds of situations that the Certificate does not apply. For example, we are still required to report child abuse and some diseases, and we must make data available to the government for a review or evaluation of our research. The Certificate does not prevent you or a member of your family from voluntarily sharing information. Similarly, if an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Questionnaires
You may feel uncomfortable answering questions about your medical history, education, occupation, and daily activities. You can choose not to answer questions that make you feel uncomfortable.

MRI
Some people are bothered by feelings of confinement (claustrophobia), and by the noise made by the machine during the test. You will be asked to wear earplugs or earphones while in the machine. You may not participate in this study if you have a pacemaker, an implanted defibrillator or certain other implanted electronic or metallic devices. It is important for you to tell the MRI staff if you have had brain surgery for a cerebral aneurysm, or if you have implanted medical or metallic devices, shrapnel or other metal, such as metal in your eye.

New Findings
If we learn any significant new findings during the study that might influence your decision to participate, we will contact you and explain them.

Unknown Risks
We have described all the risks we know. However, because this is research, there a possibility that you will have a reaction that we do not know about yet and is not expected. If we learn about other risks, we will let you know what they are so that you can decide whether or not you want to continue to be in the study.

Are there possible benefits to me?

You will not experience any direct benefit personally from participating in this study. We hope you will participate because the study will generate important information about the treatment of mobility cognition and provide information needed for rehabilitation of mobility and cognitive disability. The information learned from this study may, in the future, help advance scientific knowledge about cognitive and mobility performance in aging.

What choices do I have other than participating in this study?

You can refuse to participate in the study.

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time without giving a reason. However, some of the information may have already been entered into the study and that will not be removed.

Can the study end my participation early?

We will not let you participate in the study any more if any unanticipated serious adverse events determined to be possibly, probably or definitely related to study procedures occur. In addition, your participation will end if the investigator or study sponsor stops the study earlier than expected.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

_____	_____	_____
Printed name of participant	Signature of participant	Date
_____	_____	_____
Printed name of the person conducting the consent process	Signature	Date