ALBERT EINSTEIN COLLEGE OF MEDICINE

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called **Social Dancing Intervention for older adults at high risk of Alzheimer's disease and other dementias.** 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 researchers in charge of this project are called the "Principal Investigators." Their names are **Dr. Joe Verghese** and **Dr. Helena Blumen**. You can reach Dr. Verghese or Dr. Blumen at:

1225 Morris Park Avenue, # 308
Bronx, NY 10461
Telephone: 718 430-3978

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, by e-mail at irb@einstein.yu.edu, 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
National Institutes of Health

Why is this study being done?

The goal of this study is to evaluate whether ballroom dancing and/or treadmill walking programs can improve cognitive (learning, understanding and remembering) difficulties among senior citizens. This study aims to determine if seniors show improved cognition following the program.

This study compares two interventions. One group will participate in a ballroom dancing program. The other group will participate in a treadmill walking program.

This study will provide important information regarding the usefulness of ballroom dancing compared with treadmill walking programs to maintain cognition and prevent cognitive decline. Contrasting ballroom dancing with treadmill walking will allow us to determine the feasibility and relative usefulness of these forms of exercise for preventing cognitive decline and improving everyday life.

Why am I being asked to participate?

You are being asked to participate in this study because you are 65 years or older and have responded to recruitment fliers posted around Albert Einstein College of Medicine, Montefiore University Hospital, or have been contacted via market mailing to a Bronx and Westchester County Registered Voter List.

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 6-month ballroom dancing program or a 6-month treadmill walking program. Both interventions consist of **2 (90-minute) classes per week for 6 months (up to 48 classes)**. Total time is 180 minutes per week. If you miss sessions during the 6-month intervention you will have the opportunity to make-up up to 4 classes at the end of the 6-month period. The ballroom dancing sessions will include a warm-up, dance class and cool down. The treadmill walking sessions will consist of a warm-up, brisk walk and cool down.

If you are eligible and agree to participate in this study, you will be invited to **five study visits** (one before the dance/walking sessions begin, one in the second month of the dance/walking sessions, one in the fourth month, one after the dance/walking sessions end, and one 3 months after the dance/walking sessions have ended). During these study visits, the study interviewer will ask you questions about your medical history, education, daily activities and occupation. You will receive tests 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 approximately 3.5 hours. If needed, testing can be completed during an additional visit.**

During two of the study visits you will also undergo **Magnetic Resonance Imaging (MRI)**. **The MRIs will take approximately 1.5 hours and will take place at Albert Einstein College of Medicine.** 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.

A description of this clinical trial will be available on www.ClinicalTrials.gov (ClinicalTrials.gov Identifier: NCT03475316), 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 about **32** people who will be participating in this study.

Will there be audio and/or video recording?

Your whole body including face may be video-taped and recorded during some evaluations. Your auditory and video recording will be given a code number and separated from your name. Your auditory recording will be kept as long as they are useful. The tapes will be used by the research team to score the evaluations and refine measurements already collected. You will not receive any monetary compensation for allowing yourself to be taped.

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 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.
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.
Information about me will be kept as long as required by regulations and institutional policy, but will not be used for future studies.

Will I be paid for being in this research study?

You will receive **$10 for each dance or walking class (48 classes), and $25 for each MRI (2 MRI visits), for a total of up to $530** for the study. If you choose to withdraw from the study before all visits are completed, you will be paid only for the visits you completed.

If you miss any of the 48 sessions you will have the opportunity to make-up up to 4 sessions at the end of the 6-month period.

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

Will it cost me anything to participate in this study?

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

What will happen if I am injured because I took part in this study?

If you are injured as a result of this research, only immediate, essential, short-term medical treatment as determined by the participating hospital, will be available for the injury without charge to you personally.

- No monetary compensation will be offered.
- You are not waiving any of your legal rights by signing this informed consent document.
- If additional treatment is required as a result of a physical injury related to the research, necessary medical treatment will be provided to you and billed to your insurance company or to you as part of your medical expenses.

Immediately report any discomforts, problems or injuries you experience during the course of your participation in the study to **Dr. Joe Verghese** and **Dr. Helena Blumen**. They can be reached at **(718) 430-3962**

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 secure manner 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
- 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 were requested or subpoenaed by government agencies or the courts, we would use the Certificate to attempt to legally refuse to provide that information. These requests are 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 to which 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 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.

Are there any risks to me?

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy – see the Confidentiality section above for details.

Treadmill training & Dance classes
Classes will be closely supervised and taught by certified instructors. A gradual approach will be applied to increase exercise intensity and levels of complexity of new dances. Your pulse and blood pressure will be assessed before and after each session to assure that the values do not change significantly from the initial assessment. You will be asked to wear sports shoes with good grip soles to each of the sessions and the instructor will inspect your footwear to ensure

that it is appropriate. If you experience any cardiovascular symptoms, excessive fatigue, discomfort, unsteadiness or balance problems during the sessions it is important to tell the instructor immediately. If you report experiencing any of these symptoms we will stop the sessions and ask that you are examined by the study clinician.

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.

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

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 may or may not receive personal, direct benefit from taking part in this study. The possible benefits of taking part in this study include improved physical fitness and possible early detection of disorders discovered as a result of evaluations during screening.

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. The researchers and the sponsor may continue to use and share the information they have already collected.

To revoke (take back) your consent and authorization, you must contact the Principal Investigators in writing at the address on page 1 of this form. However, you may first call or speak to the Principal Investigators and she/he will stop collecting new information about you. If you take back your consent and authorization, you will not be allowed to continue to participate in this research study.

Can the study end my participation early?

We will not let you participate in the study any more if **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