Study Participant ID: _____

INFORMED CONSENT AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Hebrew Senior Life / "Optimizing transcranial direct current stimulation (tDCS) to improve dual task gait and balance in older adults"**
Protocol Number:	**2019-51**
Principal Investigator:	**Bradley Manor, PhD**
Telephone:	**617-971-5332 (24 Hours)**
Address:	**Hebrew Senior Life** **1200 Centre St.** **Boston, MA 02131**

Concise Summary of Key Information

'Dual tasking' means the ability to do two things at once; for example, walking and talking at the same time. Dual tasking disrupts standing and walking in older adults. Older adults who have fallen, as well as those who have problems within mobility or balance, are more likely to have difficulty with dual tasking. Transcranial direct current stimulation (tDCS) is a safe, noninvasive technology used to stimulate brain activity, and has been shown to improve "dual tasking" in older adults. The purpose of this research is to understand, in older adults, the potential benefits of different types of tDCS on standing and walking while dual tasking.

This study involves up to 6 visits over about 8 weeks and includes four tDCS sessions, an optional MRI scan, dual-tasking tests, and assessments of memory and thinking. Risks and side effects of the procedures are minimal, and described in detail on pages 6-7.

About this Consent Form

Please read this form carefully. This form provides important information about participating in a research study. As a research participant, you have the right to take your time in making decisions about participating in this research and you are encouraged to discuss your decision with your family and your doctor. If you have any questions about the research or any part of this form, please ask us. If you decide to take part in this research, you will be asked to sign this form, and a copy will be provided for you.

What you should know about a Research Study

Participation in research is voluntary, which means that it is something for which you volunteer. It is your choice to participate in the study, or to decline participation. If you choose to participate now, you may change your mind and stop participating at a later date. Refusal to participate or withdrawal of participation will not result in any penalty or loss of benefits to which you are otherwise entitled.

Study Participant ID: _____

Study Funding and Disclosure of any Special Interests

This study is being conducted by Dr. Brad Manor. The study is funded by the National Institute of Health. Neither Dr. Manor nor Hebrew SeniorLife (HSL) have any special interests or conflicts of interest to report.

Purpose of the Research

You are being asked to participate in a research study designed to understand the potential benefits of tDCS on standing and walking while dual tasking. tDCS is a safe technology that sends very low-level electrical currents to your brain using two or more electrodes placed upon the surface of your head. It produces tingling and itching sensations in your scalp, but should not hurt or feel too uncomfortable. One, 20-minute of tDCS may increase the activity of specific parts of your brain for several hours afterwards.

You may be eligible to participate because you are between age 65-85 and report difficulty walking or maintaining your balance. We expect to enroll 36 participants in this study.

The study design is called a double-blinded, randomized controlled study. If eligible, you will receive four 20-minute sessions of different types of tDCS during the study. Two of the sessions will involve real stimulation, and two of the sessions will involve "sham' stimulation. Sham stimulation does not increase the activity of your brain. Both tDCS and sham stimulation will feel exactly alike; you will feel a tingling or itching where the sponges/electrodes are located on your scalp. We use sham stimulation to determine if tDCS is the true cause of any improvements in balance, walking and cognition.

The order in which you receive the different types of stimulation will be random. Double-blinded means that neither you nor the research staff will know which type of stimulation you are receiving at a given session. The four types of stimulation are:

1. Conventional tDCS: This type of real tDCS will be delivered using large sponges placed on specific areas of your scalp.
2. Optimized tDCS: This type of real tDCS will be delivered using several small gel-based electrodes (similar to those used during an ECG or EEG) placed on specific areas of your scalp.
3. Conventional sham: This stimulation is referred to as a placebo or "control". It does not stimulate the brain or affect brain function, but will produce similar tingling and itching sensations as real tDCS.
4. Optimized sham: This stimulation is also a placebo, but will be delivered by small gel-based electrodes placed upon your scalp. It will not affect stimulate the brain or affect brain function, but will produce similar tingling and itching sensations as real tDCS.

Research Procedures

In this research study, you will be asked to participate in the following procedures: In total, participation will include up to 6 visits over 8 weeks.

Before the first visit, we will call you to discuss participation and get some information to determine your initial eligibility to participate. For example, we will ask for some contact

information so we can be in touch. We will also ask you some questions about your health history to determine if it is safe for you to participate in the protocol. You can expect that the initial screening call to take no more than 30 minutes of your time.

Visit 1: 3 hours; Hebrew Rehabilitation Center (HRC)

This visit includes an in-person screening to confirm your eligibility to participate in the study and a baseline assessment if you are eligible to participate. We will also describe the study in detail to you. The initial screening will take approximately 30 minutes. If you are eligible to participate and are interested in continuing in the study, the remaining part of the visit will take approximately two hours and will include the baseline assessments described below.

Visit 1A: Initial screening (approximately 30 minutes):

You will be asked some questions about demographic information, mental and physical health, medications, and history of falls, habits, and daily activities. We will also measure your height, weight, and blood pressure and have you perform some dual-tasking tests

For the dual-tasking tests we will ask you to walk twice for 30 seconds at your normal walking pace: once while walking quietly, and another time while walking and counting backward by 3's out loud. We will calculate the difference between your walking speeds in each trial. *You will be eligible to participate in this study if your walking speed when dual tasking is at least 10% slower than your walking speed when walking quietly.*

Visit 1B: Baseline assessments (total time, approximately 2.5 hours):

You will be asked to complete baseline assessments, including tests of dual tasking, mobility (walking and balance), and cognition as described below. You will also be asked some questions about fear of falling, your mood, and pain. To minimize in-person time, questionnaires in the baseline assessment described below may be completed by telephone.

Dual task tests: (30 mins) We will ask you to complete the dual tasking tests similar to those described above. We will ask you to sit in a chair, stand in one spot, and walk comfortably for up to one minute at a time. We will then ask you to combine counting backwards out loud (dual task) while standing, and then while walking.

During these tasks, we will monitor your movements using equipment, called *Mobility Lab* (APDM Inc., Portland, OR), which is wireless, light-weight and uses wearable sensors on the outside of your body to record body movements while standing or walking. The sensors are attached to different parts of the body (e.g. waist, back, arms, and legs) with Velcro straps or an elastic belt.

Balance and walking: (35 mins) You will be asked to walk a few yards, stand up from a chair, and stand with one foot beside or in front of the other. You will also be asked to walk at your own pace several times, walk back to a chair and sit down. You may sit down and rest at any time during the tests if you become tired. You will be asked to stand on a stationary plate that will measure how much you sway as you are standing still. An experienced research assistant will be at your side at all times to ensure your safety during all balance and walking tests.

Memory and thinking: (60mins) At this visit you also will do some tests of memory and thinking. For example, we will ask you to do mental math, "connect the dots" task, remember a sequence of numbers, remember specific words, and to answer various questions. These tests are made to be challenging, but there is no "pass" or "fail".

Visit 2: 1 hour; Beth Israel Deaconess Medical Center (BIDMC)

Optional MRI visit

On your second visit, we will scan your brain using magnetic resonance imagining (MRI). This will be completed within the Center for Advanced MR Imaging at the BIDMC in Boston, MA. The scan will take 50 minutes and the entire visit takes about an hour. Transportation and/or parking will be arranged for you and provided at no cost (or you will be reimbursed).

The MRI machine takes pictures of the brain using a large magnet and radio signals. It allows examination of your brain without exposing you to X-rays. The MRI will consist of structural MRI scans and functional MRI scans. A structural MRI scan provides information about the shape and size of structures in the brain. A functional MRI scan provides information about the activity of the brain. These types of scans are a part of routine MRI procedures.

During the exam, you will be asked to lie down on a platform that slides into a big hollow, but narrow, tube-like machine. Only your head and upper body will slide into the machine. Foam pads will be placed around your head for cushion and to limit head movement. During the scan you will be asked to lie very still on your back for about 50 minutes. During the scanning, you will hear loud knocking or hammering noises while the MRI is taking pictures. To lessen the noise of the machine, we will provide you with earplugs. You will be able to hear and speak to the technician at any time through an intercom. The process is painless, but if at any time you are uncomfortable or need a break, please tell the technician. Also, if at any time you wish to no longer continue, for any reason, just tell the technician and the scanning will be stopped immediately and you will be removed from the machine.

The MRI done in this study is for research purposes only. It will not be read by a radiologist. If there are incidental findings noted on your MRI, you will be notified by the study team and advised to see your primary care provider for a diagnostic MRI, and a letter will be sent to you and your primary care provider.

We may need to contact your health care provider to ask him/her for documentation related to whether it is safe for you to have an MRI of your brain. For example, if you've had cataract surgery, we would need to verify the name, make, and model of the lens that was implanted. This is for safety purposes. If we need to contact your health care provider we will ask you for your written permission to do so. In the event that you are not eligible to have an MRI you may still be eligible to continue in the study.

Study Participant ID: _____

Visit 3 to Visit 6: 90 minutes per visit to Hebrew Rehabilitation Center:

The remaining study visits (3, 4, 5 & 6) will involve real or sham brain stimulation at each visit and dual-tasking tests before the stimulation, and twice after the stimulation. You will be asked to complete one visit per week for four weeks in a row, for a total of four visits.

tDCS stimulation sessions: (20 mins) The type of brain stimulation we will be using is called *transcranial direct current stimulation* (tDCS). A tDCS-certified research assistant will administer all tDCS sessions while you sit quietly in a chair. The tDCS device is programmed to send a very-low-level electric signal between two or more electrodes, which will be placed on your head (over top of your hair). A small amount of water-soluble gel will be placed beneath each electrode. This will help the communication between electrodes and prevent scalp irritation. See below for information about all potential side-effects of tDCS.

Dual task tests: (30 mins) We will ask you to complete the dual task tests as described above just before the tDCS session, right after the tDCS session, and then again one hour later.

For this we will ask you to sit in a chair, stand in one spot, and walk comfortably for up to one minute at a time. We will then ask you to combine counting backwards out loud (dual task) while standing, and then while walking.

Visit	Purpose	Procedures	Study Personnel	Duration	Location
Visit 1	Screening visit	1A: Health and cognitive assessments; Dual tasking eligibility testing; IF eligible 1B: Baseline Dual task tests; Balance and walking tests; Memory and thinking tests	Study RA	3 hours	HRC
Visit 2	MRI scan (optional)	MRI scan	MRI technician	1 hour	BIDMC
Visit 3 – Visit 6	Intervention and dual tasking assessment visits	tDCS brain stimulation visit; Conventional tDCS; Optimized tDCS; Conventional sham; Optimized sham. Dual task balance and walking assessments before, immediately after, and one hour following the stimulation.	Study RA	90 mins each	HRC

Study Participant ID: _____

Return of Research Results

During this research we may learn information from the study results which could be important for your health or your treatment. This information will be made available to you and/or your health care provider. The information we may share is information from your MRI scan if, during the scan, an incidental finding is identified that requires follow-up. IF this happens, we will call you and let you know about it, and send you and/or your health care provider a follow-up letter so that you may follow up with your health care provider.

Risks and Discomforts of Participating in the Research

This study will take a considerable amount of your time, but the health risks of participation in the study are minimal.

Tests of walking and physical Function: These tests have been used successfully in several large-scale studies in the past and have been designed to be safe for individuals of varying risk and condition. The physical activity associated with these tests is of low to moderate intensity. Potential risks include strains, sprains, muscle soreness, and light-headedness. In rare instances, more serious side effects including a fall may occur.

During all tests of walking and physical function, a trained "spotter" will stand or walk close to you in order to provide assistance if needed. You will also be allowed as much rest as needed in between each test.

Tests of mental function, cognition and mood: You will be asked to complete mental tasks and tasks of cognition to the best of your ability. There is no pass or fail to these questions. You will also be asked questions about your current and past feeling of happiness, sadness and motivation. Risks associated with answering these questions are minimal, but you may experience mental fatigue and/or anxiety during this form of testing.

If, during the study, we have reason to believe that you are at risk for being suicidal or otherwise harming yourself, we are required to take the necessary actions. This may include notifying you, your family member, your therapist(s) if applicable, or other individuals. If this were to occur, we would not be able to assure confidentiality

Magnetic Resonance Imaging (MRI): The presence of metal objects in your body could cause a burn or other injury. As such, we will follow strict MRI guidelines to minimize risk. You will fill out a standard MRI safety checklist and you will not complete the MRI if you have, or are at risk of having, certain metal objects in your body. It is therefore very important that you tell us if there is any metal in your body. You may feel claustrophobic or anxious during the procedure and/or experience muscle or back discomfort lying on the scanner table. Please let the technician know if you experience any discomfort or pain during the procedure.

Study Participant ID: _____

The MRI makes loud banging noises as it takes images. To make images with an MRI scanner also requires the use of radio waves that can cause a mild warming similar to exposure to hot weather. Body temperature may increase slightly but less than two degrees Fahrenheit. Please tell the technician if you feel discomfort due to warming and the procedure will be stopped.

Transcranial Direct Current Stimulation (tDCS): The safety of tDCS has been tested by researchers who have concluded that when it is used in a manner similar to the way it will be used in our study, it is safe. Reported short-term side effects of tDCS may include temporary headache, dizziness, nausea, itchiness and irritation under the area of electrodes. If you experience any of these side-effects, or anything other discomforts, please tell the researcher. There are no known long-term negative side effects of tDCS.

You will be informed of any significant new findings developed during the course of this research which may affect your willingness to continue participation.

If, during the study, we have reason to believe that you/your family member are at risk for being suicidal or otherwise harming yourself, we are required to take the necessary actions. This may include notifying you, your family member, your therapist(s) if applicable, or other individuals. If this were to occur, we would not be able to assure confidentiality.

You will be informed of any significant new findings developed during the course of this research which may affect your willingness to continue participation.

In Case of Injury while Participating in the Research

We will offer you the care needed to treat any injury that directly results from taking part in this research study. If we cannot provide the care directly, we will arrange for the care to be provided to you at a nearby institution. We (and/or the treating provider, as appropriate) reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury beyond what is described above, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of the study as soon as possible. The researcher's name and phone number are listed at the end of this consent form.

Study Participant ID: _____

Benefits to Participating in the Research

You may not directly benefit from this study, but others may benefit from the knowledge gained in connection with your participation. This study may add to the overall scientific knowledge of tDCS as a potential non-invasive intervention to improve physical and cognitive function in older adults.

Alternatives to participation

This research study is for research purposes only. The only alternative is to not participate in this study.

Confidentiality of Information Collected as Part of the Research

All personal information obtained in the study will be kept confidential, and this information will only be available to the research staff. The records identifying your name will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. The results of the study will only be published or presented as group data. No individual participants will be identified. Forms to collect data will be identified with a unique study number and kept locked in the study office.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Study Sponsor, the Food and Drug Administration, and the Advarra Institutional Review Board, or others in order to meet regulatory requirements.

Certificate of Confidentiality

The National Institutes of Health (NIH) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless: there is a law that requires disclosure (such as to report child abuse or communicable diseases, but not for legal proceedings); you have consented to the disclosure, including for your medical treatment; or the research information is used for other scientific research, as allowed by federal regulations protecting research participants.

Disclosure is required, however, for audits or program evaluations requested by the agency that is funding this project or for information that may be required by the Food and Drug Administration (FDA). Any research information that is placed in your medical record would not be covered under this Certificate.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If others obtain your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

Study Participant ID: _____

Future Use of Biological Specimens or Data

Identifiable samples and/or identifiable private information collected from you during this study may be used for future research studies or shared with other researchers for future research. The identifiable samples and/or identifiable private information may be used for future research to understand and improve function in those who fall with balance, walking or memory problems. If the research investigator distributes your samples and/or information to other researchers or institutions, your samples and/or information will be labeled with a research code without identifiers so that you cannot be identified. No additional consent will be requested for the future use of your samples or information.

(1) I agree to allow the following information and materials collected from me for this research study to be stored and used for future studies to understand and improve function for those with in those who fall with balance, walking or memory problems: Data from physical and mental assessments.

___Yes ___ No

(2) I agree to allow Dr. Brad Manor to keep my contact information and contact me in the future with information about new research opportunities. I understand that I am not obligated to participate in the future and can request to not be contacted at any time.

___Yes ___ No

Compensation for Participating in the Research

You will receive up to $300 for your participation in this study. Specifically, you will receive the following amounts for each visit you complete:

- Visit 1A - In-person screening - $25
- Visit 1B - Baseline Assessment - $25
- Visit 2 – Optional MRI visit - $50
- Visits 3- 6: Brain stimulation and Dual tasking assessment visits – one visit per week for 4 weeks; $50 for each visit = total of $200

You should receive the check in the mail within eight weeks of study participation. If you do not receive a check within this timeframe, please contact the PI, Dr. Brad Manor.

Costs to Participating in the Research

There are no costs to you for participating in this study.

Withdrawal from the Research

Your participation in this research is completely voluntary. If you chose not to participate or withdraw from the study, you will incur no penalty or loss of usual benefits. You may withdraw your consent and discontinue participation at any time without affecting your employment, job evaluations, health care or other services you may be receiving. If you choose to take part in the study, you have the right to stop at any time.

Your participation in this research project may be terminated if the procedure is determined to be inappropriate or potentially harmful for you.

Study Participant ID: _____

Authorization for Use and Disclosure of Your Protected Health Information

As part of this study, we will be collecting and sharing information about you with others. Please review this section carefully as it contains information about the federal privacy rules and the use of your information.

Protected Health Information (PHI)

By signing this informed consent document, you are allowing the investigators and other authorized personnel to use and disclose health information about you. This may include information about you that already exists such as: such as demographic information, as well as any new information generated as part of this study through questionnaires, tests, procedures that we may ask you to undergo. This is your Protected Health Information, or PHI.

People/Groups at HSL Who Will Use Your Protected Health Information

Your Protected Health Information, PHI, may be shared with the investigators listed on this consent form as well as the supporting research team (i.e. research assistants, statisticians, data managers, laboratory personnel, administrative assistants). Your PHI may also be shared with the Advarra Institutional Review Board as it is responsible for reviewing studies for the protection of the research subjects.

People/Groups Outside of HSL with Whom Your Protected Health Information Will Be Shared

We will take care to maintain confidentiality and privacy about you and your Protected Health Information, PHI. We may share your PHI with the following groups so that they may carry out their duties related to this study:

- The sponsor of this study National Institute of Health and their clinical research organizations
- Other hospitals and medical centers taking part in this study Beth Israel Deaconess Medical Center
- Your health insurance company, for portions of the research and related care that are considered billable.
- Federal and state agencies that oversee or review research information, such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities.
- Data and Safety Monitoring Board(s) that oversee this study.

Those who receive your PHI may make further disclosures to others. If they do, your information may no longer be covered by the federal privacy regulations.

Why We Are Using and Sharing Your Protected Health Information

The main reason for using and sharing your Protected Health Information is to conduct and oversee the research as described in this Informed Consent Document.

Study Participant ID: _____

No Expiration Date - Right to Withdraw Authorization

Your authorization for the use and disclosure of your Protected Health Information, PHI, in this Study shall never expire. However, you may withdraw your authorization for the use and disclosure of your PHI at any time by notifying the Principal Investigator in writing. If you would like to withdraw your authorization, please send a letter notifying the Principal Investigator to Dr. Brad Manor at 1200 Centre Street, Boston, MA 02131. Please be aware that the investigators in this study will not be required to destroy or retrieve any of your PHI that has already been used or disclosed before the Principal Investigator receives your letter.

Right to Access and Copy Your PHI

If you wish to review or copy your Protected Health Information, PHI, as it is made part of your medical record, you may do so after the completion or termination of the study by sending a letter to the Principal Investigator. You may not be allowed to inspect or copy your PHI until this study is completed or terminated.

Notice of Privacy Practices

In addition to signing this document, you may also be asked to sign an HSL Acknowledgement Received Notice of Privacy Practices form to acknowledge that you have received the HSL Notice of Privacy Practices.

ClinicalTrials.Gov

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.

Whom to Contact About This Study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Study Participant ID: _____

Please reference the following number when contacting the Study Subject Adviser: Pro00044371.

Documentation of Informed Consent and Authorization:

- I have read this consent form and was given enough time to consider the decision to participate in this research.
- This research has been satisfactorily explained to me, including possible risks and benefits.
- All my questions were satisfactorily answered.
- I understand that participation in this research is voluntary and that I can withdraw at any time.
- I am signing this consent form prior to participation in any research activities.
- I give permission for participation in this research and for the use of associated protected health information as described above (HIPAA).

Research Participant

_____ _____

Date (MM/DD/YEAR) Signature of Research Participant

Investigator or Associate's Statement & Signature:

- I have fully explained the research described above, including the possible risks and benefits, to all involved parties (participant as applicable).
- I have answered and will answer all questions to the best of my ability.
- I will inform all involved parties of any changes (if applicable) to the research procedures or the risks and benefits during or after the course of the research.
- I have provided a copy of the consent form signed by the participant and a copy of the hospital's privacy notification (if requested).

_____ _____

Date (MM/DD/YEAR) Signature of Investigator or Associate

Study Participant ID: _____

Witness Statement & Signature:

Required ONLY IF (check which one applies):

☐ Consent document needs to be read to subject, **or**

☐ Communication impairments limit the subject's ability to clearly express consent, **or**

☐ Other reason: please specify: _____

I confirm that the information in this consent form was accurately explained to, and understood by the subject as required, and that informed consent was given freely.

_____ _____

Date (MM/DD/YEAR) Signature of Witness