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INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

Please read this form which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study?

Augmenting Cognitive Training in Older Adults: The ACT Study.

3. Who do you call if you have questions about this research study?

Principal Investigator: Adam J. Woods, PhD Phone- 352-294-5842

24 hour contact number- 772-206-0576

Andrew O'Shea- 352-294-5827

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4. Who is paying for this research study?

The sponsor of this study is the National Institute of Aging of the National Institute of Health (R01AG054077).

5. Why is this research study being done?

The purpose of this research study is to examine a mild form of brain stimulation called *Transcranial Direct Current Stimulation (tDCS)* and its effect on thinking and memory improvement with brain training in older adults. The specific study purpose is to determine whether brain training outcomes can be further improved with very mild brain stimulation, using a technique which has been shown to be safe.

This Brain Stimulation activity will be combined with Brain Training, which is like playing computerized games designed to challenge your thinking and memory skills. Brain stimulation (tDCS) involves placing two sponge like electrodes on your head. These electrodes will deliver a very weak electrical current to your scalp from a small device that operates on a 9V battery.

Even very healthy, normal aging older adults often complain of having trouble with thinking and memory activities; like remembering a grocery list or a phone number. This combination of brain training and brain stimulation activities may help improve thinking and memory skills in some people. This study is designed to look at the combinations that may work best.

You are being asked to be in this research study because you are 65 years of age or older and healthy with no neurological diseases or brain diseases, and willing to participate in a combination of brain stimulation and brain training. You are also being asked to participate in this research study because you are willing and able to have an MRI of your brain and willing to participate in memory and thinking tasks designed to measure your thinking and memory ability before and after the training periods.

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.

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WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?

Normal clinical care is medical care that you would receive from your doctors even if you did not participate in this research study. There will be NO clinical care provided as a research participant in this study. You will still need to see your personal doctor for any medical care that you need.

The activities that you participate in are all for research data collection only, and not to treat or cure you of any disease or medical problem

7. What will be done only because you are in this research study?

During the study, you will be asked to participate in:

1. ***Three Assessment Visits*** to gather information about your thinking and memory processes will be scheduled at your convenience. The assessments will be done exactly the same way at the start of your study time, after three months of training and stimulation, and again around one year after you began the research study.

The first visit will be to review this informed consent document, answer all questions that you may have regarding the research study. If you would like to take this form home to discuss with family and friends before you start the study, you may do that too. When you are ready, we will complete other screening tasks and questionnaires designed to determine if this is a good study for you to participate in. The next assessment may include a detailed review of your health history, and other tasks and surveys that give us a first look at how your brain works in many different areas of thinking and memory. We will also ask you to participate in an online memory and thinking game type program called NIH Toolbox, and other activities that are similar to the things you do on a daily basis, like withdrawing money from a bank machine. These assessment visits will be scheduled again at three months and one year from your start time, and may take up to 8 hours each (may be split over two days if desired), depending on your need for breaks and rest periods.

2. ***Training*** – Participants will be randomly assigned [much like a flip of a coin] to one of two training conditions: 1) cognitive training or 2) educational training.

    2.1 Cognitive Training (CT): CT will take place over a three month period and you will be asked to perform around 40 minutes of brain training computerized games per weekday. We will teach you everything you need to know and assist you with learning how to do your Brain

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Training assignments. You do not need to have any other experience in operating a computer or participating in Brain Training games and there will be plenty of help throughout the study.

2.2 Educational Training (ET): ET will take place over a three month period and you will be asked to watch around 40 minutes of educational videos from the National Geographic Channel per weekday. After the videos you will be given a short set of questions on the content of the video.

Computer use - Training at home will require a special computer that has a screen size of at least 14 inches (diagonal) and access to the internet. We will provide you with a computer, mouse and headphones for use during the three-month period of the study. You will be required to return the computer and supplies at the end of the three-month training period. We will provide you with Internet access built into the computer.

Returning the Equipment - You will be required to return the University of Florida computer and any other equipment loaned to you during this study, at the end of the three-month training period or if you discontinue participation. You will be asked to bring it with you on your last visit, if you forget or discontinue participating, we will provide you with mailing supplies so that you can return it at no cost to you. If you do not return the computer, or lose the computer, a report must be filed with the University Police Department, and City of Gainesville Police department, for lost or stolen University equipment. This is a very serious crime at the University of Florida, so we will request your absolute participation in returning the equipment when you are finished. We will ask you for a copy of your driver's license today, to keep on file in case a report must be filed later.

Do you agree with allowing us to make a copy of your driver's license today to keep in your file, and that you will return all equipment as instructed above?

YES ☐

NO ☐

If you do not agree with these University policies for returning equipment, you will be unable to participate in this particular research study. There are many other studies that you may be able to participate in at another time.

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3. ***Brain Stimulation -*** In combination with either brain training or educational training, you will also be randomly assigned to one of two different Brain Stimulation groups.

As a participant, you will be randomly assigned (much like the flip of a coin) to receive either the full length session of brain stimulation (active stimulation) or a shorter session of brain stimulation (sham stimulation). The shorter version of stimulation looks like and is performed in the same way as the longer electrical stimulation session, but stimulation is stopped before it can have much of an effect on the brain. The stimulation technique called *transcranial direct current stimulation (tDCS*) involves placing two sponge-like electrodes on your head and delivering a very tiny, weak electrical current to your scalp, which is generated by a 9V battery. We will take a brief set of pictures of your head after the electrodes are placed on your head to make sure that the electrodes are in the correct location. These photos will be used to create a 3D model of your head that will give us accurate information about where the electrodes were placed. You will be asked to wear a small wristband during stimulation sessions. This wristband provides non-invasive physiological recording such as pulse.

If you decide to take part in this study, you will be randomly assigned (much like the flip of a coin) to receive either active stimulation or placebo (sham stimulation). A placebo is a substance that looks like and is given in the same way as an experimental treatment but contains no medicine, for example [a sugar pill, an injection of saline (salt water)]. A placebo is used in research studies to show what effect a treatment has compared with taking nothing at all. If you are assigned to receive placebo, you will not receive the benefits of the active stimulation if there are any, nor will you be exposed to its risks, which are described below under "What are the possible discomforts and risks?" Studies have shown, however, that about 1 in 3 persons who take a placebo do improve, if only for a short time. You and the physician and other persons doing the study will not know whether you are receiving placebo or active stimulation but that information is available if it is needed. Also, you will have a 50% chance of receiving active stimulation and a 50% chance of receiving placebo. In the remainder of the description of what will be done, both the active stimulation and the placebo will be called "study treatment."

Both versions of the stimulation may cause an effect in some people, improving memory and thinking, or making the brain more ready to learn, and one type of stimulation may have effects that last longer than the other. It's possible the stimulation will have no positive benefit in some individuals. Some people may notice a slight tingling or itching at the sight of the electrodes, but it should not be painful at all, and stops immediately when the current is stopped. If this bothers you, the stimulation level can be turned off. Remember, you can stop the research study at any time you no longer want to participate. You will not know which group

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you have been assigned to while participating in the research, but you may find out at the completion of the research study.

MRI Brain Scan is used to see pictures of your brain and determine which areas of the brain are being used and which areas may be improving from the training and stimulation sessions. This will be done at 3 separate appointments, at your convenience, around the same time as the 3 Assessment Visits. You may be asked to participate in a few thinking and memory activities during the time your brain is being imaged. During the MRI scan you may be asked to perform a series of short breath holds, where you are restricting your breathing for a short time; this will allow us to measure a signal for further analyses. The time for the MRI will be approximately one hour, and scheduled depending on your availability. MRIs will be performed at the McKnight Brain Institute (MBI). Ensuring your comfort while in the MRI is a priority for our staff, and you will be able to communicate with them while you are having the brain scan by voice over a speaker. They will make you feel as comfortable as possible while participating in the scan with blankets or padding as needed.

Other Information on the Activities listed:

Screening. General screening measures are done to determine if your hearing, vision, color vision, memory and MRI compatibility are all ok for participation in the study. We will review a list of drugs to be sure you are not currently prescribed any medications that will interfere with the study.

If you are found not to be able to continue with the study as a result of the screening procedures your participation in the study is finished. No further data will be collected from participants who do not meet inclusion requirements. Even if you do not meet inclusion requirements, any protected health information that was collected after the signing of this form will be kept by study staff and handled in a secure manner as described in sections 17-21 of this form.

We appreciate the interest and effort of all potential participants. However, no compensation will be provided to those who are not eligible to participate. The full details of compensation are described in section 15 of this form.

Questionnaires. You will be asked about your medical history through a detailed questionnaire, another questionnaire about your quality of life, questionnaires asking you about your cognitive and physical abilities, computer experiences and about your mood and daily activities. You will be asked questions about your mental health including if you are depressed or suicidal. You will be asked questions about your past and current alcohol and drug use to help us understand how they might alter the effects of brain stimulation, cognitive training and education training. These questionnaires may take approximately 1 hour. There will also be a questionnaire asking you to rate how you felt during and after brain stimulation every time you visit the lab.

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Tests of thinking and memory. You will perform a series of computerized and paper/pencil tasks that evaluate your thinking and memory abilities. These tasks and measures may last approximately 3 hours.

Tests of your functional abilities. You will perform a computerized battery of tests that test abilities important for everyday function in older adults. For example, these tests will look at how well you can use an automated teller machine for banking (ATMs), set up doctors' appointments, or order prescriptions. These tests will last approximately 2 hours.

Tests of your physical abilities. You will perform a ten-meter walk test. This test involves walking at your normal walking pace (using a cane or walker if applicable) over a ten-meter (approximately thirty feet) course. You will walk the course two times, while an experimenter times you.

Transcranial direct current stimulation (tDCS). tDCS is a form of brain stimulation that involves passing a weak electrical current across the scalp. This weak electrical current can stimulate the brain and is being evaluated in its role to help learning new tasks. You will have one tDCS brain stimulation session per day for 2 weeks, followed by ten weekly sessions in our laboratory.

Daily Laboratory Training Visits. For the first two weeks of the study you will be asked to come in every week-day (10 visits). During the forty minutes of laboratory brain training each day, you will also be asked to participate in twenty minutes of brain stimulation at the same time. After stimulation you will be asked to fill out a questionnaire asking you will rate how you felt during stimulation and in the period before stimulation. After the first two weeks of training finish, you will come into the laboratory only once per week for the remaining ten weeks. Additionally, you will be asked to complete 4 days per week (2 hours and 40 minutes) of training at home.

Daily brain training will take place in our laboratory at the McKnight Brain Institute or our laboratory at the Village at Gainesville. You will discuss your preferred study location with the study staff.

If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

Tests done only for research purposes will not be evaluated or used to diagnose or treat any of your medical problems. This/these test(s) may need to be repeated if required for your medical care in the future.

Driving Records. This study will collect information about driving outcomes. We would like to obtain a copy of your driving record from the Department of Motor Vehicles. This report will contain information such as car accidents, traffic violations/ citations, criminal violations related to driving, and the status of your driver's license. Following the study we will request driving records twice, once at five-year and once at ten-year intervals. We will need your consent to access this information. Providing access to driving records is completely voluntary. If you decline consent to driving records request you can still participate in the study.

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Do you provide consent to having your driving record requested?

YES ☐

NO ☐

Video Recording. We would like permission to take video or photos of your assessment and intervention sessions. These videos or photos will be used to assess the quality of our assessment administration and intervention visits and will be reviewed by experts at the University of Florida to provide feedback to the experimenters on their performance. Do you give permission to have quality control videos or photos taken during your assessment or intervention visits? These videos will not be released and will only be accessible by study investigators.

YES ☐

NO ☐

Potential Long Term Follow-up. We would like your permission to contact you back five years after your enrollment in this study. You are free to decline long term follow-up and still participate in this current study. If you consent to be contacted back in five years please check YES below.

YES ☐

NO ☐

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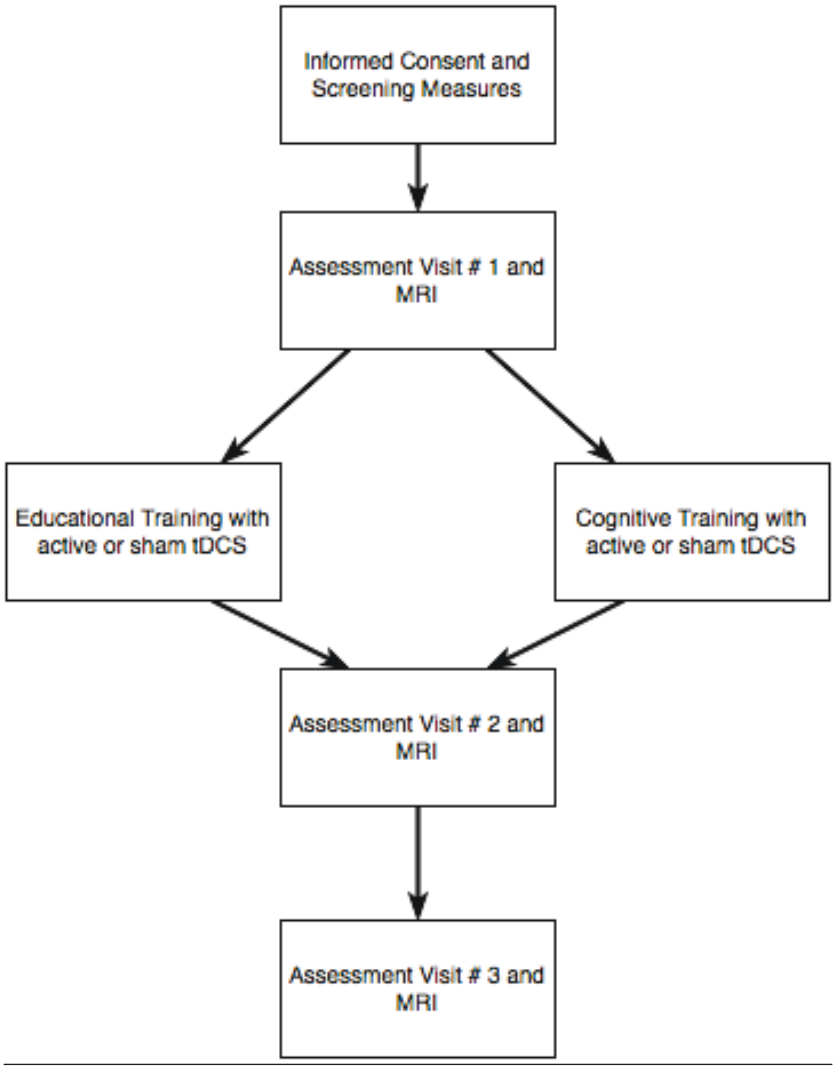
Summary Flow Chart of Study Appointments:



8. How long will you be in this research study?

You will participate in the active phase of the study for approximately one year. This will involve a screening visit, baseline assessment visit, three months of either cognitive training or educational training with lab visits, a three-month follow-up visit and a one-year follow-up visit. Each assessment visit will last approximately 8 hours. See the figure on the next page for a month-by-month timeline. If you consent to be contacted for long term follow-up your participation will last approximately five years.

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Single Subject Timeline	Month														
	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Phone Screening															
Consent Form															
Screening															
Baseline Measurements															
Cognitive Training/tDCS															
Post-CT Measurements															
1 Year Follow-Up Measurements															

9. How many people are expected to take part in this research study?

Approximately 1,116 people are expected to take part in this study in total. Approximately 744 people are expected to participate at the University of Florida. Of the 744 potential participants, we expect approximately 264 to be eligible for the study intervention.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

10. What are the possible discomforts and risks from taking part in this research study?

Magnetic resonance imaging (MRI). MRI is a procedure that allows doctors to look inside the body by using a scanner that sends out a strong magnetic field and radio waves. This procedure is used routinely for medical care and is very safe for most people, but you will be monitored during the entire MRI scan in case any problems occur. The risks of MRI are:

- The MRI scanner contains a very strong magnet. Therefore, you may not be able to have the MRI if you have any type of metal implanted in your body, for example, any pacing device (such as a heart pacer), any metal in your eyes, or certain types of heart valves or brain aneurysm clips. Someone will ask you questions about this before you have the MRI.
- There is not much room inside the MRI scanner. You may be uncomfortable if you do not like to be in close spaces ("claustrophobia"). During the procedure, you will be able to talk with the MRI staff through a speaker system, and, in the event of an emergency, you can tell them to stop the scan.
- The MRI scanner produces a loud hammering noise, which has produced hearing loss in a very small number of patients. You will be given earplugs to reduce this risk, and headphones for added protection.

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- If an obvious abnormality is discovered during your MRI scan, you will be informed about it by the research team's primary investigator, Dr. Woods, and you will be provided with a copy of your MRI scan and referral to an appropriate specialist for further follow-up and examination. MRI will only be done for research purposes in this study, and is not used to treat or diagnose any conditions.
- You will be monitored very carefully while in the scanner, and repeatedly checked to ensure comfort.

Brain Stimulation. This type of Brain Stimulation is considered safe and has been used in more than 3000 research subjects around the world. This type of stimulation has not caused serious side effects. Our study uses techniques that are considered safe and procedures that have been safely employed by prior research at the University of Florida, and University of Pennsylvania. The FDA has ruled that the Brain Stimulator used in this study is a "non-significant risk" device. A small number of people do experience some side effects. The most common side effects are itching and tingling or mild discomfort at the area of stimulation, and headache. Other possible side effects include dizziness and nausea. Whenever an electrical stimulation is applied to the body, it could possibly cause a seizure or abnormal heartbeat, but this has never occurred, or been reported in the research conducted anywhere in the world, while using the brain stimulation levels used in this study.

To minimize risk associated with Brain Stimulation, participants will be monitored throughout stimulation sessions and asked to report any discomfort. If scalp sensation is uncomfortable, stimulation will be stopped. In the event of a headache, stimulation will be stopped. All sessions will be administered and continually supervised by a trained experimenter. The above symptoms have only been reported when participants are actively being stimulated. However, to assess for any symptoms occurring during the period between stimulation sessions, we will administer a brief symptom screening questionnaire at the beginning (symptoms in the past week) and end of each session (symptoms during stimulation). Brain Stimulation has not been shown to cause seizures nor lower the seizure threshold in animals. There are no reports of seizure induced by Brain Stimulation, in human participants in the literature. However, this may not be true for epilepsy patients and they will not be included in this study for safety reasons.

Brain training. There is a risk you will find cognitive training on the computer challenging, fatiguing, and/or boring. Research staff will explain what to do and how to perform the training tasks tests during your initial study visit. You will also have access to a 24-hour help line should you have trouble working with the training computer.

Educational training. There is a risk you may find ET to be challenging, fatiguing, and/or boring. Research staff will be present to address any concerns. You are free to skip any content you find objectionable and refrain from answering any questions that you find uncomfortable. All material presented has been judged appropriate for an educational setting.

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Memory and Thinking and Functional tests. There is a risk that you will find memory and thinking and functional tests challenging, because it may be difficult to remember the things that you are asked to remember or have trouble hearing or seeing some of the sounds and pictures presented on the computer screen. You may skip any tests you do not wish to complete. Research staff will explain what to do and help you take the tests during your study visit.

Questionnaires. There is a risk that you will find questions on the questionnaires uncomfortable to answer. You may skip any question you feel uncomfortable answering. If you indicate active plans for suicide, you will be immediately referred to the study psychologist (Dr. Ron Cohen, PhD) for further assessment.

In this study we will ask you questions about previous and current alcohol and drug use. These questions are of a particularly sensitive nature. There is a risk that you may be uncomfortable answering such questions. Like any other part of this study, you are free to decline to answer anything that you are uncomfortable with.

Other possible risks to you may include fatigue due to the testing. Should this occur, you can take a rest-break at any time or you may discontinue the testing at any time.

When being tested some people may develop anxiety. If these tests make you anxious we can stop the testing.

Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information (for example, illegal drug use or driving while intoxicated charges), such a release could upset or embarrass you, or possibly affect your insurability or employability. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project. If you are currently participating in another study using transcranial direct current stimulation or transcranial magnetic stimulation, you will be rescheduled so that your participation in the current study does not overlap with your participation in the other study.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 in this form.

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11a. What are the potential benefits to you for taking part in this research study?

You may or may not benefit from participating in this study. A potential benefit from the cognitive training and active stimulation could be improved working memory and cognitive ability.

11b. How could others possibly benefit from this study?

This study will help us understand whether cognitive abilities in healthy older adults can be improved with computerized brain training programs and if brain stimulation provides greater improvement. This could impact how we treat age-related decline in thinking and memory problems in older adults.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 of this form may benefit if the results of this study are presented at scientific meetings or in scientific journals.

12. What other choices do you have if you do not want to be in this study?

Your participation in this study is entirely voluntary. You are free to refuse to be in the study and your refusal will not influence current or future health care you receive at this institution or anywhere else.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you withdraw from this study, your research information will no longer be collected. However, information that has already been collected will continue to be used to the extent that the researchers have used it in this research study.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

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- Failure to meet the inclusion criteria or meeting the exclusion criteria for this study.
- Failure to comply with the instructions given to you by the investigators.
- Failure to complete all testing sessions.
- The study is discontinued for administrative reasons.
- Should you develop a health condition that could interfere with your participation
- Investigator may determine that it is not in your best interest to continue

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

Study Services

The Sponsor will provide all services required as part of your participation in this study. There will be no cost to you. If you receive a bill related to this study, please contact Adam J. Woods, PhD Phone- 352-294-5842.

Items/Services Not Paid for by the Sponsor

All other medical services provided to you that are not directly required by this study will be billed to you or your insurance company in the usual manner.

15. Will you be paid for taking part in this study?

You will receive $75 in gift cards at the end of each of the three MRI sessions to compensate your time and effort in the present study and to cover any travel related expenses.

If you are paid more than $75.00 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. If the payments total $600.00 or more or you are a nonresident alien, payment will be processed through the University of Florida Accounts Payable department and the University must report the amount you received to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: http://privacy.ufl.edu/SSNPrivacy.html

Your payment for participation in this research study is handled through the University of Florida's Human Subject Payment (HSP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (HSP) Program site is limited to certain staff

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with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

The study team will provide you with an informational form called the Prepaid Card Facts document. If you have any problems regarding your payment call the HSP Office (352) 392-9057.

16. What if you are injured because of the study?

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact Dr. Adam Woods at 352-294-5842 or one of the research team members listed in question 3 of this form at 772-206-0576 if you experience an injury or have questions about any discomforts that you experience while participating in this study.

17. How will your health information be collected, used and shared?

If you agree to participate in this study, the Principal Investigator will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization. The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future

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health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your study visits and telephone calls. More specifically, the following information may be collected, used, and shared with others:

- Past medical history, including brain and nervous system disorders, psychiatric disorders, heart related disorders, and other significant disorders
- Current medications
- Study results
- Age
- Sex
- Handedness
- Education level
- Social security number for the purposes of payment
- Phone number
- Email
- Driver License

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.

18. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others for the following study-related purpose(s):

- To examine the effects of brain stimulation (tDCS) on brain training in seniors.

Once this information is collected, it becomes part of the research record for this study.

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19. Who will be allowed to collect, use, and share your protected health information?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- the study Principal Investigator (listed in question 3 of this form) and research staff associated with this project.
- other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures.
- the University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).

20. Once collected or used, who may your protected health information be shared with?

Your PHI may be shared with:

- the study sponsor (listed in Question 4 of this form).
- United States governmental agencies who are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections in the case of audits or study reviews.

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

21. If you agree to take part in this research study, how long will your protected health information be used and shared with others?

Your PHI will be used and shared with others until the end of the study.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about

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you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

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SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization	Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing	Date