Cover Page

O+icial Title: Brain Networks of Turning Performance with Aging and Stroke

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Department of Veterans Affairs | VA RESEARCH CONSENT FORM | UF

Subject Name: _____ **Date** _____

Title of Study: Brain Networks of Turning Performance with Aging and Stroke

Principal Investigator: Clayton W. Swanson, Ph.D., M.S. **VAMC:** North Florida/South Georgia Veterans Health System

UF Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM

to Participate in Research

INTRODUCTION

Name of person seeking your consent: _____

Place of employment & position: _____

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

For PI Use:

Participant Social Security Number: _____

SSN should be written on this consent form by the research team prior to scanning into the VHA health record; if the subject does not have a VHA health record, this requirement is N/A.

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2. What is the Title of this research study?

Brain Networks of Turning Performance with Aging and Stroke

3. Who can you call if you have questions concerns, or complaints about this research study?

Principal Investigator:
Clayton W. Swanson, Ph.D., M.S.
352-376-1611 x107538 (office phone)
503-887-9745 (mobile phone)

Other research staff:
David J. Clark, Sc.D.
352-376-1611 x105244 (office phone)
352-443-0655 (mobile phone)

4. Who is paying for this research study?

The sponsor of this study is the US Department of Veterans Affairs, Rehabilitation Research and Development Service.

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. 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** or the North Florida/South Georgia Veteran's Health System Research Service Office at (352) 548-6069.

a) In general, what is the purpose of the research, how long will you be involved?

You are already a participant in the "CONTROL Study" (IRB201803010), and we are inviting you to join this add-on study so that we can collect extra information to understand how the brain controls turning during walking. We will study the brain using a technique called transcranial magnetic stimulation (TMS).

Volunteers who qualify will be invited to attend one additional three-hour study visit.

b) What is involved with your participation, and what are the procedures to be followed in the research?

Example of TMS participant set up and seat

We assess how the brain helps to control turning during walking. Transcranial magnetic stimulation (TMS) is a method that can give information about how easily the neurons in your brain can respond to input, and how those neurons communicate with your muscles. This is a safe method, and is generally comfortable to most people. In addition, you will be asked to perform a series of maximal contractions of your shin muscles on each leg. You will also be asked to complete questionnaires asking about your ability to complete activities of daily living and independence.

While TMS is being delivered, you will be comfortably seated and be asked to perform a series of slight muscle contractions of your shin muscles (like what is seen in the picture).

c) What are the likely risks or discomforts to you?

TMS is considered safe unless you have contraindications such as metal implants or devices in your body, or you have a history of seizures. We will screen you for these items prior to conducting TMS. Some people experience a headache and/or neck stiffness from a TMS session, but this is temporary and uncommon.

d) What are the likely benefits to you or to others from the research?

There is no direct benefit to those who participate in this study.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

The only alternative is not to participate in the study.

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Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study

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.

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 or other treatment or services that you would receive even if you did not participate in this research study. Nothing in this research study is part of your normal clinical care.

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

Participants who qualify will be invited to attend 1 visit The visit will include:

Questionnaires:
You will be asked to fill out two questionnaires. These questionnaires will ask you about your ability to complete activities of daily living and your ability to complete tasks independently.

Transcranial Magnetic Stimulation (TMS) testing:
We will have you sit comfortably in a chair, and we will tape small sensors to the skin of your legs to measure your muscle activity. We will then have you slightly contract ("flex") your leg muscles while we simultaneously deliver transcranial magnetic stimulation (TMS). During TMS we hold a device next to your head (it looks sort of like a paddle), and that device can create a small magnetic field. The type of TMS that we use is called "single pulse" and "paired pulse" which means that the magnetic field only lasts a brief moment, and causes a quick period of brain activity. When this happens, you may feel a sensation like one or two taps on your scalp. It does not hurt, but may feel unusual. Most people are not bothered by the sensation, but if it makes you uncomfortable you do not have to continue the test.

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The brain activity may cause a single twitch in your muscles, which we can measure using the sensors taped to your legs. For our experiment, you will receive test stimulation(s) every 5-7 seconds for each 3-minute trial. We also provide several rest periods lasting a few minutes each. The entire TMS test lasts about an hour and a half including breaks.

If any identifiable information was collected as part of this research, it is possible that your research information, with all personally identifiable information removed, could be used for future research studies, or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

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

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

If you meet the eligibility criteria and decide to enroll, you will be asked to complete 1 study visit lasting 3 hours.

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

We expect up to 50 people to complete the TMS study visit. A larger number will complete the screening visit but will not qualify for TMS administration.

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?

Falls. There is a slight chance that you may experience a fall getting into or out of the TMS chair. To limit this chance the chair can be lowered, and research staff can help to safely guide you into the chair. Once you are seated in the chair, you will be secured using a seatbelt like harness.

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Headache. Although rare, the most common side effect from TMS brain stimulation is headache. You should not participate if you have a history of migraine or other types of severe or frequent headaches. It is also possible that you will experience some neck stiffness or neck pain. If so, the likely cause will be the prolonged duration of holding your head and neck in the same position throughout the hour and half of testing. If you experience a headache or neck stiffness, you could consider taking over-the-counter pain medication which should resolve your symptoms.
Seizure. The event of experiencing a seizure is very rare, especially for those who do not have a personal or family history of seizures, a known seizure disorder, or are taking medications which lower the seizure threshold. We will make sure to appropriately screen you to make sure you are not at any increased risk of experiencing a seizure. As of 2020, the rate of experiencing a seizure was 8/100,000 people for all types of TMS including repetitive TMS which is a technique that will not be performed.

TMS is a safe, non-invasive brain stimulation technique that can be used for both diagnostic and therapeutic procedures. The single and paired pulse TMS techniques that will be performed in this study have been used extensively in thousands of research studies and on tens of thousands of participants in the United States and around the world. Single and paired pulse TMS techniques are considered very safe when accepted guidelines are followed, and no long-term risks have been reported involving the use of single and paired pulse TMS. For most people, the stimulation is not painful, but occasionally slight discomfort or headache can occur. The TMS machine makes a clicking sound, so we will ask you to wear earplugs during TMS to ensure that the clicking noise does not bother your hearing. Other risks have been reported with a different form of this technique called repetitive TMS (rTMS). However, we do not use rTMS. ***If you are uncomfortable with the TMS testing, you may discontinue it at any time***.

TMS can interfere with implanted medical devices and will not be done in people who have pacemakers, implanted pumps, or stimulators, such as cochlear implants or in people who have metal objects inside the eye or skull (dental work such as fillings and similar procedures do not pose a risk and are acceptable). Please inform the investigators if you have any of these or known hearing loss. ***If metal is present or you have an implanted device or metal object that is not safe for TMS, you will not be allowed to participate.***

Finally, there is no medical risk associated with the surface EMG recordings of the muscle responses to TMS.

It is not possible to identify all potential risks in research procedures, but the researcher(s) have taken reasonable safeguards and trainings to minimize any known and potential, but unknown, risks.

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 such a release could upset or embarrass you, or possibly even affect your insurability or employability.

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 consent form or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of any new information that may become available and might affect your decision to remain in this study. This includes, but is not limited to, information that may affect your safety, well-being or medical care.

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

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

There are no direct benefits for participation in this study.

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

Others may benefit if we can increase our knowledge of how the brain contributes to successful walking and turning function. This may lead to future studies to assess longer term rehabilitation techniques for improving mobility function.

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 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?

The other choice is not to participate in the study. If you do not want to be in this study, please tell a member of the research team and do not sign this consent form.

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:

- The Principal Investigator feels that continuation could be harmful to you.
- You do not qualify to be in the study because you do not meet the study requirements. Ask the Principal Investigator if you would like more information.
- There is a change in your health and physical functioning making it difficult for you to comply with the protocol.

- You need treatment not allowed in the study.
- Unforeseen problems affecting administration of the research project.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

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

There is no fee for participation, but there may be incidental costs related to participation such as gas for commuting to the study visits, food, etc.

There will be no costs to you for any procedure, treatment or testing done as part of this research study. However, medical care and services provided by the VA that are not being done only for this study (e.g., normal hospital and prescription expenses which are not part of the research study) will be charged to you or your insurance. These costs may not be charged if you are a veteran and you are being treated at the North Florida/South Georgia Veterans Health System (NF/SG VHS), however some Veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to VA-provided medical care and services that are not part of this study."

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

Enrolled participants will be paid $40 for attending the TMS study visit.

Additional compensation per visit will be paid to participants traveling from more than 25 miles away (one-way). Round-trip travel compensation is calculated using the current VA travel reimbursement rate times mileage as determined by Bing Maps using the fastest and shortest route from your home to the Brain Rehabilitation Research Center ("door-to- door"). Compensation at the current rate calculates to $20.75 per visit for 50 miles round trip.

Payment process: Subjects enrolled in research studies at the VA receive study related compensation as an electronic transfer of money to a bank account (direct deposit). The compensation for your participation in this research study will be direct deposited from the VA Finance Office to your verified bank account.
If you are already set up to receive any other VA benefit payments electronically, then there is nothing you need to do. If you are not already set up to receive VA

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benefit payments directly to your bank account, then you will need to complete a "Vendor Form for EFT Payments (Direct Deposit)," and turn it in or mail it to the VA Finance Office. This form will require your name, address, social security number, phone number, email address, valid bank account number and routing number for verification before study payment can be processed. In addition, you may also be sent a secure email from the VA Finance Office asking you to confirm the bank account details you provided. Your response to this email will be required for setting up the payments. Payment may instead be issued through a debit card that we provide to you. This option will be at the discretion of study staff, such as for individuals who have no prior financial relationship with the US Dept. of Veterans Affairs. The debit card option requires disclosing your name and contact information to the financial institution that manages the debit card program.

If you do not complete this step, you may still participate in this study, but you will not be paid.

Note: You may be responsible for paying income taxes on any payments provided by the study. Any payment made to you on a VA-funded study, regardless of amount, must be reported to the Internal Revenue Service (IRS) because the payment system cannot distinguish payment from reimbursement for expenses. Please ask your tax advisor if you have any questions about your taxable income.

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

If you experience an injury or illness as a result of your participation in this VA approved research study, all medical treatment considered necessary by your physician (emergency as well as medical treatment beyond emergency) will be provided by the VA. There will be no cost to you, unless you fail to follow the directions of the study procedures. Care will be provided at a VA medical facility unless the VA medical facility is not capable of providing the care. If this occurs, you will be treated by a private facility or physician and the VA will pay the private facility or physician for the reasonable cost of your care. In some cases the VA may approve private care for a non-veteran.

If you do not follow study procedures, you may be treated by the VA on the basis of your veteran's eligibility. If you are not a veteran and have not followed study procedures the VA can only provide limited care at your expense.

No additional money has been set aside for pain, suffering or any money losses you may suffer during your treatment. You have not waived any legal rights by signing this form.

In the event of a research-related injury, have questions about any discomforts that you experience while participating in this study or if you experience an adverse reaction, please immediately contact the Principal Investigator listed in question 3 of this form during the day at 352-376-1611 and after business hours at 503-887-9745. If you seek emergency hospitalization in a private hospital because you are unable to come to the VA, have a family or friend contact your study doctor so that the VA can coordinate care with the private hospital.

17. How will your privacy and the confidentiality of your research records be protected?

Information collected about you will be stored in locked filing cabinets or in computers with security passwords. Only certain people have the legal right to review these research records, and they will protect the secrecy (confidentiality) of these records as much as the law allows. These people include the researchers for this study, certain University of Florida officials, the hospital or clinic (if any) involved in this research, and the 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). Certain federal agencies such as the Office for Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), or the VA Office of the Inspector General (OIG), that oversee human subject research may also have the legal right to review your records. Otherwise your research records will not be released without your permission unless required by law or a court order.

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 such a release could upset or embarrass you, or possibly even affect your insurability or employability.

If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.

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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 alternatives to being in the study; and how privacy will be protected:

_____ _____

Signature of Person Obtaining Consent 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 privacy will be protected. 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 other questions at any time.

You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

_____ _____

Signature of Person Consenting Date