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: _____

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?

rTMS for Dystonia and Tremor

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

Principal Investigator: David Vaillancourt, Ph.D. at 352-294-1770

Other research staff: Felix-Antoine Savoie at (352) 294-1771

4. Who is paying for this research study?

This study is sponsored by the National Institutes of Health and the University of Florida.

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.

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

The purpose of this research study is to find out how repetitive transcranial magnetic stimulation (rTMS) can help people with Dystonia and tremor. rTMS is a noninvasive way of stimulating the brain using a magnetic field. In this study, we will find out how rTMS affects electrophysiological activity by monitoring brain waves with Electroencephalography (EEG) before and after applying rTMS. You will be asked to come to our researcher's lab at the University of Florida for (1) one or (2) two testing session(s) for approximately 6-8 hours each visit.

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 Website at any time.

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

During the experiment, you may be asked to complete the following: (1) questionnaires about depression; (2) tests to measure your strength and motor function; (3) tests to measure your cognition; (4) measurement of your body movements using the Ambulatory Parkinson's Disease Monitoring (APDM) sensors; (5) measurement of your brain waves using a non-invasive technique called electroencephalography (EEG); (6) measurement of your muscle activity using another non-invasive technique called electromyography (EMG); and (7) stimulation to your brain using a technique called transcranial magnetic stimulation (TMS).

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

The research has several risks and discomforts:

Stimulation from rTMS may cause headaches, neck aches, temporary hearing loss and in some cases fainting. There is a theoretical risk of inducing a seizure and the risks to an unborn fetus are not known. Because of the current induced by the magnetic field, you may not be able to receive stimulation if you have metal implanted in your body (such as a heart pacer).

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

You may or may not benefit from taking part in this study. The rTMS may have a short-term benefit on your tremor or dystonia, and our goal is to understand the mechanism under which that this occurs. The information learned in this study will benefit the neurology and therapy development community.

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

Participation in this study will still allow you to continue your normal course of treatment prescribed by your physician.

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.

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)?

None of the study activities will be done as part of your normal clinical care.

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

During the experiment, you may be asked to complete the following: (1) questionnaires about depression; (2) tests to measure your strength and motor function; (3) tests to measure your cognition; (4) measurement of your body movements using the Ambulatory Parkinson's Disease Monitoring (APDM) sensors; (5) measurement of your brain waves using a non-invasive technique called electroencephalography (EEG); (6) measurement of your muscle activity using another non-invasive technique called electromyography (EMG); and (7) stimulation to your brain using a technique called transcranial magnetic stimulation (TMS).

EEG is a technique that measures electrical potentials produced by your brain. We place small sensors on the outside of your head, that will contact gel, and this will create an environment to measure the electrical activity occurring in your brain. We have you do specific tasks to measure changes in your brain activity.

TMS is a technique that stimulates the brain by changing a magnetic field that produces an electrical stimulation in a specific part of the brain. We are using TMS in this study to change the activity of the motor cortex and/ or cerebellum region to see how this affects tremor and dystonia and the activity in this region. If you are asked and agree to participate for a second testing session, we will wait at least (1) one week after your first visit to use TMS to the cerebellum region.

Orientation Session:

We will explain the study to you, review the informed consent document and answer questions you may have about the study. If you agree to participate in this research, we will begin gathering data.

Clinical Measures:

We will gather data about your age, gender, height, weight and medical conditions. If you have a movement disorder, we will gather data about your clinical movement disorder history. You will be asked to complete forms that test your neurological status including the TRG Essential Tremor Rating Assessment Scale (TETRAS), which permits us to rate the severity of tremor and the Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) that measures disease disability and pain. With your permission, these rating scales will be video recorded to ensure rating reliability. You will be asked to take tests that assess your cognitive abilities and emotional status. The cognitive tests measure abilities such as comprehension, memory and attention. The emotional status test will assess your current level of depression.

Physical Performance Measures:

You will be asked to walk a short distance and stand in place with small sensors that will be placed on your body (ex: chest, legs, arms, etc.). The test will measure your movement while you are walking a short distance.

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.

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. By agreeing to participate in this study, you are agreeing to complete the following items.

Medical history

Tests to measure your cognition (mental capabilities)

Questionnaire about depression

Tests to measure your motor function

TRG Essential Tremor Rating Assessment Scale

Toronto Western Spasmodic Torticollis Rating Scale

Measurement of your brain responses with EEG

Measurement of your muscle activity with EMG

Stimulation of your brain (Cortex) using a technique called transcranial magnetic stimulation (TMS) (Dystonia and Tremor Participants Only)

Stimulation of your brain (Cerebellum) using a technique called transcranial magnetic stimulation (TMS) (Dystonia and Tremor Participants Only)

Please sign below to indicate that you agree to the above plan:

_____

Signature of participant

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

You will be asked to come to our researcher's lab at the University of Florida for (1) one testing session. The study visit should last approximately 6-8 hours. The study coordinator and staff will build in breaks for you, and will provide you with refreshments, snacks, and lunch. You may be asked to participate for a second testing session lasting 6-8 hours if you will receive rTMS to both motor cortex and cerebellum. You will receive motor cortex rTMS on first day and cerebellar rTMS on the second day. The second day testing will occur at least (1) one week after your first visit.

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

We expect to enroll 90 participants in our study. We will enroll 30 healthy control participants and 60 participants diagnosed with dystonia and/or tremor.

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?

This is study might involve the following risks and discomforts to you:

TMS:

- Headaches – Headaches and neck aches can occur. They can be related to stabilizing the neck when measuring TMS. They are usually short lasting and respond easily to over the counter analgesics.
- Transient hearing threshold shift – There is a possibility of temporary mild hearing loss due to the noise of the TMS machine. The rate of this risk is unknown yet. Earplugs will be provided to you to reduce the potential for this risk.
- Seizure – A theoretical risk associated with brain stimulation. In clinical trials using the NeuroStar TMS Therapy® System, which included over 10,000 TMS treatments, no seizures were reported. Since FDA clearance of the NeuroStar Therapy System, the seizure risk is ≤0.1% per patient (less than 1 in 1000

patients). In the event that you have a seizure, the study staff will immediately stop the treatment session and make sure that you are safe during the seizure. You will be watched for a period of time after the seizure to make sure you are feeling well. Individuals with an active seizure disorder are excluded.

- Fainting – It is possible that fainting could occur from anxiety and psycho-physical discomfort during the procedure. It is not directly related to the TMS but can be related to one's perception of receiving the TMS. The laboratory is equipped and staff is trained to respond to this risk if fainting occurs. However, you will be at very low risk (less than 1%) for fainting. Transfer to the emergency room might be needed if you fail to improve as expected.
- Implanted Devices – The TMS could interfere with implanted devices (such as pacemakers, deep brain stimulation leads or cochlear implants). To avoid this potential complication, you will be excluded from the study if you have metallic implants such as pacemakers, implants, metal rods or hearing aids.
- Childbearing Potential – There may be unknown risks to the fetus. Therefore, you must complete a pregnancy test for the TMS portion of the study. A negative pregnancy test does not absolutely prove that you are not pregnant. You should not participate if you think there is a possibility that you might be pregnant. If prior to your participation in this study you think you have become pregnant, you must immediately notify the study investigator, David Vaillancourt. Nursing mothers are not eligible for participation in this project. The possibility exists that complications and undesirable side effects, which are unknown at this time, could occur.

EEG:

- A gel paste is used to attach the sensors during EEG which may mildly and briefly irritate the skin on the scalp or face. Hair products cannot be used on the day of testing (or should be washed out prior to testing), which may be inconvenient to you.

EMG:

- A gel paste is used to attach the sensors during EMG which may mildly and briefly irritate the skin.

Testing Day Activities:

- If the Beck Depression Inventory reveals that you have feelings of harming yourself, we will refer you to mental health services available at Shands at the University of Florida.
- For the measurement of your body movement with the APDM, you may lose your balance or fall while standing with hands on hip and walking a short distance. The study staff will keep a close distance to avoid any falls. A gait-belt would be used if needed.

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

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

You may or may not benefit from taking part in this study. The rTMS may have a short-term benefit on your tremor or dystonia, and our goal is to understand the mechanism under which that this occurs. The information learned in this study will benefit the neurology and therapy development community.

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

Information from this study might help researchers develop better treatments using rTMS and EEG to help others with Dystonia and tremor in the future.

11b.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 alternative to taking part in this study is to not participate. If you do not want to take part, tell the Principal Investigator or study staff and do not sign this Informed Consent Form.

13. 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.

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

If you withdraw from this study, no further data will be collected; however, information already collected will still be used.

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

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

- You may be withdrawn from the study without your consent if the principal investigator feels it is necessary
- If you are pregnant or might be pregnant
- If you have a history of seizure disorders
- If you have any type of implanted electrical device (such as cardiac pacemaker or a neurostimulator), or a certain type of implants

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 pay for all activities 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 Dr. David Vaillancourt at (352) 294-1770.

Items/Services Not Paid for by the Sponsor

All other medical services provided to you that are not directly related to the study will be billed to you or your insurance company. You will be responsible for paying any deductible, co-insurance, and/or co-payments for these services, and any non-covered or out-of-network services

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

You will be paid $80.00 for taking part in our (1) one-day study. If you are asked and choose to participate in a second visit, you will be paid an additional $80.00 for taking part in our (2) two-day study. In addition, you will be reimbursed for your travel costs (such as flights, hotels, and/or reimbursement for gas) if you live a minimum of 50 miles away from Gainesville. Finally, during long testing sessions, food and beverages for you and any family members and/or caregivers that accompany you to the visit will be provided at no expense to you.

If you are paid more than $75 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 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 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.

University employees are no longer paid through the University payroll system. Instead, UF employees will be paid in a manner consistent with other participants in this research study.

If you withdraw from the study, you will still receive payment.

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 the Principal Investigator listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

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). 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.

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

Consent to be Photographed, Video and/or Audio Recorded

With your permission, you will have the following done during this research (check all that apply):

☐ photograph ☐ video recorded ☐ audio recorded

Your name or personal information will not be identified on the photograph(s), video or audio recordings, and confidentiality will be strictly maintained. However, when these photograph(s), video and/ or audio recordings are shown or heard, others may be able to identify you. The video and audio recordings will only occur during the clinical scales acquired.

The Principal Investigator (PI) of this study, Dr. David Vaillancourt, or his successor, will keep the photograph(s), video and/or audio recordings in a locked cabinet, in a folder on a password protected computer server drive, or as an encrypted electronic file. These photograph(s), video and/or audio recordings will be shown under his direction to students, researchers, doctors, or other professionals and persons.

Please indicate under what conditions Dr. David Vaillancourt has your permission to use the photograph(s), video and/or audio recordings, and sign and date below.

☐ The following will be **destroyed once the study is closed** (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

☐ As described in the Informed Consent Form, and for the purposes of **education at the University of Florida Health Science Center**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

☐ As described in the Informed Consent Form; for the purposes of **education at the University of Florida Health Science Center; and for presentations at scientific meetings outside the University**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

_____ _____

Signature Date