Title: Physiology, Imaging and Modeling of Essential Tremor

ClinicalTrials.gov ID: NCT03811405

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UF | Institutional Review Board
UNIVERSITY of FLORIDA

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?

Physiology, Imaging and Modeling of Deep Brain Stimulation for Essential Tremor

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

Principal Investigator: Joshua Wong, MD at (352) 273-5550

Please call (352) 264-8408, ask for the neurologist on call for 24-hour assistance.

4. Who is paying for this research study?

The sponsor of this study is the Department of Neurology. Medtronic is supplying the programmer and software program.

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 study is to test the effectiveness of a particular stimulation pattern on patients implanted with a deep brain stimulation (DBS) device who are diagnosed with Essential Tremor.

b) What is involved with your participation, and what are the procedures to be followed in the research? Your visit will be similar to a typical clinic visit except the duration will be much longer. We will record your current DBS settings, then turn the DBS off for 30 minutes and begin the various stimulation patterns. Your participation will last one half day in clinic.

c) What are the likely risks or discomforts to you? Possible discomforts could occur as a result of taking part in this study from the different stimulation patterns. These possible discomforts could be similar to common programming side effects such as under stimulation, feeling of tightness, sensory issues such as numbness, tingling, or double vision. These can also occur as part of your regular visit. The side effects are stimulation-induced, transitory and pass quickly, since they can be stopped immediately by either turning the device to a lower setting, turning the device off, or returning the device to the normal setting that you use at home.

d) What are the likely benefits to you or to others from the research? You may possibly experience improvement in your symptoms with some of the settings used during this 2-4 hour study, though no long-term benefits should be expected. It is not the aim of this study to change any of your stimulation parameters permanently and we will restore the previous settings at the conclusion of the visit. We will also assist you with any clinical needs or answer any questions in relation to your movement disorder or programming.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you? The alternative options that are available at this time for Essential Tremor that does not respond well to DBS is repeat surgery to replace the DBS lead or add an additional DBS lead.

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)?

You will continue to receive standard of care treatment for your essential tremor.

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

We will record your current DBS settings, then turn the DBS off for 30 minutes and begin the various stimulation patterns.

An investigational temporary software update will be downloaded onto your Medtronic DBS device. The download takes less than 2 minutes and can be removed in less than 45 seconds. The temporary software update will be removed at the end of the 2-4 hour study. You will continue to use the settings that were set on your device as part of regular clinic care after the study procedures are complete. After removal of the temporary software update from your Medtronic DBS device it will be necessary to restore your previous therapy settings using a commercial programmer.

We will try various stimulation patterns on your DBS device. You will not know which pattern we are testing.

We will leave on the stimulation pattern for 10 minutes and begin the following assessments:

Tremor Rating Scale – the study doctor will exam the degree of tremor in the head, body, arms and legs when you are at rest, while holding a posture and while moving.

You will be asked to walk down the GaitRite mat in the clinic. The mat will measure and record your gait or walking pattern.

During these assessments, you will be videotaped so that another movement disorders neurologist can assess the severity of your tremor in a non-biased fashion. It is a requirement of this study to be video recorded. If you do not wish to be video recorded, you cannot be in the study.

We will also use the images taken before your DBS surgery for further analysis.

Additionally, clinical information from your medical record including disease characteristics and patient demographics will also be collected to be analyzed alongside all the above information.

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.

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens 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 the 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?

Your participation could last up to half a day at the Fixel Center for Neurological Diseases.

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

We expect to screen 70 patients in order to enroll 25 patients.

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?

Possible discomforts could occur as a result of taking part in this study from the different stimulation patterns. These possible discomforts could be similar to common programming side effects such as under stimulation, feeling of tightness, sensory issues such as numbness, tingling, or double vision. These can also occur as part of your regular visit. The side effects are stimulation-induced, transitory and pass quickly, since they can be stopped immediately by either turning the device to a lower setting, turning the device off, or returning the device to the normal setting that you use at home.

You will be performing gait and balance activities which can cause exhaustion. The personnel of the study are highly trained in working with tremor patients and will remain physically close to you at all times to prevent any fall-related injuries.

There are no other foreseeable significant risks to you in this study.

Other possible risks to you may include: There are no other foreseeable significant risks to you in this study.

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 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.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to remain in the 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.

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

No long-term symptom relief or battery life benefits should be expected from participating in this study. You may possibly experience improvement in your symptoms with some of the new settings used during this 2-4 hour study, but at the end of the study the original settings will be put back on the stimulator; so no symptom or battery life benefits should be expected.

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

Participation in this study may benefit other future patients with deep brain stimulation devices because new DBS settings could be identified that preserve the length of battery life and improve clinical symptoms. Increasing battery life could decrease the number of surgeries needed for battery replacements associated with your device.

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?

If you do not want to be in the study, the alternative is to continue to receive your standard care for your tremor.

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?

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 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.

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

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

- If the study will adversely affect your health.
- If the study is deemed not appropriate for your condition by your clinician.

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 or provide all study services/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. Wong at (352) 273-5550.

Items/Services Not Paid for by the Sponsor

Any 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 manner15. Will you be paid for taking part in this study?

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

You will not be paid for taking part in this study.

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 one of the research team members 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 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 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:

- The clinical benefits during the assessments: Tremor Rating Scale, GaitRite analysis achieved during the different programming settings, and the information on the physiology of your movement.
- Demographics
- Neurological exam results
- A videotape of your motor symptoms
- DBS information such as the battery use and programming information
- DBS Surgical history
- CT and MRI images taken before and during surgery
- Your general disease characteristics and demographic information
- Name, date of birth and medical record number

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):

- For the purpose of establishing a diagnosis and determining your eligibility for the study.
- To test effectiveness of active biphasic stimulation on tremor symptoms

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

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 .

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 study is completed

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 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.

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

Consent to be Video Recorded

With your permission, we would like to video record your sessions during this research.

Your name or personal information will not be identified on the video recordings, and confidentiality will be strictly maintained. However, when these video recordings are shown or heard, others may be able to identify you.

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

Please indicate under what conditions Dr. Wong has your permission to use the video recordings, and sign and date below. Please select one option below.

☐ As described in the Informed Consent and required for participation, the following will be **destroyed once the study is closed**:

_____ video 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 video recording for up to 6 years after the study is over in a locked file, in a password protected computer server drive, or as an encrypted electronic file

_____ video 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 video recording for up to 6 years after the study is over in a locked file, in a password protected computer server drive, or as an encrypted electronic file

_____ video recording(s)

_____ _____

Signature Date