Informed consent document

OFFICIAL STUDY TITLE	Open trial of median nerve stimulation for treatment of Tourette syndrome
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INFORMED CONSENT DOCUMENT

Project Title: Open trial of median nerve stimulation for treatment of Tourette syndrome

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- If you are the parent/guardian of a child under the age of 18 who is being invited to participate in this study, the word "you" in this document refers to your child. As the parent/guardian, you will be asked to read and sign this document to give permission for your child to participate.
- If you are under the age of 18 and reading this document, the word "you" in this document refers to you. You will be asked to read and sign this document to indicate your willingness to participate.

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form, you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

KEY INFORMATION

The first section of this document contains some key points that the research team thought you would find important. The research study is described in more detail after this section.

This is a research study conducted by Kevin Black, MD having to do with a potential treatment for individuals with a chronic tic disorder (CTD), including Tourette syndrome. You should carefully consider the information in this consent document and discuss it with the research team. Be sure you understand why you might want to participate, or why you might not want to participate. You may choose to participate or not.

If you agree and sign this consent, you will be volunteering to participate in the research study. All the information below will be explained and is listed in more detail in the consent document below. The research team must give you a copy of this signed consent document.

How will this study affect me?

- The long-term purpose of this research is to study a potential future treatment for individuals with a chronic tic disorder (CTD) that, if effective and well tolerated, would increase their quality of life.

- If you volunteer, your participation will last approximately four weeks, including one initial study visit lasting approximately 60 minutes. The initial study visit will be at Barnes-Jewish Hospital or Washington University School of Medicine (or may be virtual, if you have already completed both visits in the MNS pilot study). You will complete the remaining four weeks of the study online. The four weeks will start immediately after your initial study visit.

- You were selected because you are between the ages of 15 and 65 years old and you were a participant of the "Peripheral induction of inhibitory brain circuits to treat Tourette's" pilot study (MNS Pilot).

- You will be in this study for approximately four weeks.

    - ***Initial Visit*** These procedures may happen at the end of your second study day in the MNS pilot study or on a separate in-person or virtual visit.
    - This visit will begin as a screening visit to determine whether or not you may continue in the study.
    - After a brief screening, we will review the informed consent document with you. You will have a chance to ask any questions you may have.
    - At this time, you may be asked to complete one questionnaire.
    - You will then be shown how to use the TENS unit.
    - We will then attach the electrodes to your wrists and determine the stimulation threshold.
    - Lastly, we will give you a chance to ask any questions. Then we'll ask you to demonstrate operating the TENS unit on your own.

    The Study procedures for the initial visit will take place at Barnes-Jewish Hospital or Washington University School of Medicine. Directions and parking will be provided.

    On-line Participation
    The four-week portion of your study participation will be on-line. During this time, you will be asked to:
    - take the device home to use for four weeks,
    - fill out very brief surveys daily whenever you turn the device on and off, as well as at two other points throughout the day,
    - respond to text messages, and
    - complete a survey at the conclusion of the study.
- The main risks to you are discomfort, mild skin irritation, and boredom. More detail about risks is provided below.
    1. The most common risks are: discomfort in the forearm, wrist or hand during active stimulation and/or mild skin irritation from applying or removing the surface electrodes.
    2. The less likely risks are: the questionnaires and interview may be slightly boring, fatiguing or challenging.
    3. The least likely risks are: discomfort when answering questions and accidental exposure of your private health information.

- You will be paid for participating in this study. You will be given the TENS unit to keep at the successful conclusion of the study, a value of approximately $30, to compensate for your loss of time.

- There will be no costs to you for participating.

- If you withdraw from the study, the research team may continue to use information already collected about you in this study.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this research study is to study a potential future treatment for individuals with a chronic tic disorder (CTD) that, if effective and well tolerated, would increase their quality of life. We invite you to participate in this research study because you are between the ages of 15 and 64 years old **AND** you meet criterial for Tourette's Disorder **OR** Persistent (Chronic) Tic Disorder according to the DSM-5 AND you previously participated in the MNS Pilot study.

This study uses the TENS-7000 device, which is approved by the U.S. Food and Drug Administration for treatment of pain. However, the use of the TENS-7000 device is considered investigational in this study.

WHAT WILL HAPPEN DURING THIS STUDY?

If you participate in this study, you will come in to see us for one in-person visit that usually will happen at the end of your final visit to the MNS pilot study, and then four weeks of on-line study participation including daily surveys and text messages. The information below will tell you more about what will happen at this first visit.

Initial Visit

This visit may take up to 1 hour. Study procedures will take place at at Barnes-Jewish Hospital or Washington University School of Medicine**.**

- Upon arrival we will review the informed consent document to make sure that your questions are answered. If you choose to continue in the study, adult participants will provide informed consent and children will assent to participate.
- If more than 2 weeks have elapsed since the most recent administration of the Adult Tic Questionnaire, participants will be asked to repeat it. We will review the questionnaire with you.
- We will explain use of the TENS unit, including which settings you may change and which settings should remain as set by the investigator.
- Then we will attach the electrodes to your wrist to determine the appropriate amount of electrical current to deliver.
- Finally, we will verify that you are able to set up and turn on the device on your own.

Completing the initial visit should take up to 60 minutes.

On-line Participation

The four-week portion of your study participation will be online. During this time, you will be asked to:

- take the device home to use for four weeks,
- fill out very brief surveys daily whenever you turn the device on and off, as well as at two other

points throughout the day,
- respond to text messages, and
- complete a survey at the conclusion of the study.

You are free to skip any questions that you would prefer not to answer.

Will you save my research information to use in future research studies?
We would like to use the data we are obtaining in this study for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding Tourette's Disorder and/or Persistent (Chronic) Tic Disorder, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your information provided in questionnaires and on-line surveys, you give up any property rights you may have in the information provided in questionnaires and on-line surveys.

We will share your information provided in questionnaires and on-line surveys with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

Your information provided in questionnaires and on-line surveys will be stored without your name or any other kind of link that would enable us to identify which sample(s) or data are yours. Therefore, it will be available indefinitely for use in future research studies without your additional consent and cannot be removed.

HOW MANY PEOPLE WILL PARTICIPATE?
Approximately 38 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?
If you agree to take part in this study, your involvement will last for approximately four weeks. This study involves one initial visit to Barnes-Jewish Hospital or Washington University School of Medicine (in some cases, this visit may be done virtually). For the remaining four weeks, your participation will be on-line.

Online Participation
1. You will complete online measures (on a web browser) at the following times:
    a. Turning on the stimulator
        i. Tic intensity
        ii. Tic frequency

b. Turning off the stimulator
    i. Tic intensity
    ii. Tic frequency
    iii. Discomfort from stimulation
    iv. Overall symptom improvement

Texts will be sent to you twice daily at predetermined times, and you will respond with questions "c." or "d." below depending on whether the stimulator is on when you receive the text:

c. Answering a text, stimulator currently on
    i. Tic intensity
    ii. Tic frequency
    iii. Discomfort from stimulation
    iv. Overall symptom improvement
d. Answering a text, stimulator currently off
    i. Tic intensity
    ii. Tic frequency

2. You may be contacted throughout the study for reminders regarding compliance or assistance in troubleshooting issues with the device or surveys.

Online at Conclusion of Study

1. The study concludes 4 weeks after the initial visit.

2. You will be asked to complete the following additional measures:
    a. Current symptom status
        i. Adult Tic Questionnaire
        ii. Premonitory Urge for Tics Scale

    b. Treatment efficacy and side effects
        i. Modified Clinical Global Impression – Efficacy Index
        ii. Your perception of the duration of improvement after stimulation
        iii. Your plans to continue using the device
    c. Open-ended comments
        i. On device
        ii. On study

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

MNS

Likely / Common:

- Discomfort in the forearm, wrist or hand during active stimulation
- Mild skin irritation from applying or removing the surface electrodes

Questionnaires

Likely/Common:

- The questionnaires may be slightly boring, fatiguing or challenging.
- The questionnaires will take some time (about a minute each time)

Rare:

- The questions that you are asked during this study could make you feel uncomfortable. If any question makes you feel uncomfortable, you may choose not to answer it.
- Confidential information about you may be accidentally disclosed. However, we think the risk of accidental disclosure is small. The information we gather during the course of the study is coded only by a study number and is kept separately from your name, address, etc. The exception is that your phone number will be shared with Twilio.com, the text services provider we contract with. However, we do not share any other personal or identifying information with Twilio.com.

Women Capable of Becoming Pregnant

If you are a woman capable of becoming pregnant, you must use effective birth control methods and try not to become pregnant while participating in this study. If you become pregnant, there may be unknown risks to your unborn child, or risks to your unborn child that we did not anticipate. There may be long-term effects of the treatment being studied that could increase the risk of harm to an unborn child. You must tell the doctor if your birth control method fails while you are on the study. If you believe or know you have become pregnant while participating in this research study, please contact the research team member identified at the top of this document as soon as possible. Please discuss with the research team how long you need to wait before becoming pregnant after completing the treatment or procedures on this study.

Breach of Confidentiality

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because your participation will allow us to learn more about a new treatment for CTD. In the future, these studies may aid clinical management of tic disorders.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could seek treatment from your healthcare provider (many efficacious treatments exist, including specific behavior therapies and medications) or you could use this or another TENS unit on your own.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?
The sponsor is providing the TENS-7000 device at no cost to you.

You will not have any additional costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?
You will be given the TENS unit to keep at the successful conclusion of the study, a value of approximately $30, to compensate for your loss of time.
You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

WHO IS FUNDING THIS STUDY?
The University and the research team are not receiving payment from other agencies, organizations, or companies to conduct this research study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?
Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at Kevin J. Black, MD at (314) 362-5041 and/or the Human Research Protection Office at 1-(800)-438-0445.
Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University**.** If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?
Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. We will keep your participation in this research study confidential to the extent permitted by law.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Any report or article that we write will not include information that can directly identify you.

The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, your data will be coded numerically to protect individual identity. All data will be stored in locked cabinets or on computers within a private, secure network protected by a PIX firewall with remote access only permitted through virtual private network connections, as per HIPAA guidelines. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

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.

We will disclose to the proper authorities information shared with us or activities we observe concerning abuse, neglect or harm to others or yourself.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research

- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
    - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
        - **If you revoke your authorization:**
            - The research team may only use and share information already collected for the study.
            - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
            - You will not be allowed to continue to participate in the study.

Can we contact you by e-mail and text?
We would like to contact you by email and text for the purposes listed below. Some of these emails may contain health information that identifies you.

- Appointment scheduling confirmations and reminders
- Consent Forms
- Online questionnaires

Only the research team will have access to your email and text communications. We will only communicate in this method to send you the information listed above. If you have any questions, wish us to stop sending these messages or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email and text.

- Text messaging is not a secure communication method.
- There is always a risk that the message could be intercepted or sent to the wrong email address and/or phone number. To avoid this, we will send a test message to ensure we have the correct email address and telephone number.
- When using any computer, you should be careful to protect your username and password. Make sure you log out before getting up from the computer.
- If you share a home computer or cell phone with other family members, and do not want them to know you are participating in this study, make sure you provide an email address that only you can access.
- Your employer will have access to any messages sent or received on any electronic devices used for work or through a work server.
- If you lose your phone, others may be able to access the messages that we send.

Do you agree to allow us to send your health information via email?

_____ **Yes** _____ **No**
Initials **Initials**

Do you agree to allow us to send your health information via text? Sending you questionnaire links via text is an important part of the study. You may choose not to receive such messages via text, but in that case you will not be permitted to participate further in the study, except for completing the end-of-study questionnaire.

_____ **Yes** _____ **No**
Initials **Initials**

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ under Withdrawing from a Research Study.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because participating in the study is no longer in your best interest.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Emily Bihun at (314)362-2083 or emilybihun@wustl.edu . If you experience a research-related injury, please contact: Kevin J. Black, MD at (314)362-5041 or kevin@wustl.edu.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to

speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 10/18/22.

_____ _____

(Signature of Participant) (Date)

_____

(Participant's name – printed)

Parent/Guardian Name and Relationship to Participant:

Do not sign this form if today's date is after EXPIRATION DATE: 10/18/22.

_____
(Child's name – printed)

_____ _____
(Signature of Parent/Guardian) (Date)

_____ _____
(Name of Parent/Guardian- printed) (Relationship to participant – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)