Experimental Tinnitus Treatment with Transcranial Magnetic Stimulation

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Informed Consent Document

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INFORMED CONSENT DOCUMENT

Project Title: **Experimental tinnitus treatment with transcranial magnetic stimulation**

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This consent form describes the research study to help you decide if you want to participate. This form 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 as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- 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.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you have been diagnosed with chronic tinnitus. This experimental treatment uses targeted transcranial magnetic stimulation (TMS) acutely or as part of a treatment course to treat your symptoms.

The purpose of this research study is to better understand how TMS can be used therapeutically to treat tinnitus. We will use an evidenced-based approach treat your condition using existing and new neuromodulation strategies. It is hoped that this information will enable scientists and physicians to improve our knowledge of TMS and improve future treatments.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 20 people will take part in this study conducted by investigators at the University of Iowa.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for at least one treatment session that may last up to 3 hours. If the treatment is successful, we may schedule you for a full treatment course lasting up to 4 weeks. These follow-up treatment sessions would likely last less than one hour depending

on your treatment protocol.

WHAT WILL HAPPEN DURING THIS STUDY?

Background and Questionnaires: We may request medical information from prior clinical assessments regarding your current diagnosis. We would only request information that is relevant to your diagnosis that would be used to plan your treatment. Questions about your tinnitus diagnosis and history will be asked through questionnaires. We will also ask you to rate the severity of your tinnitus symptoms before, during, and after treatment sessions.

MRI: In the event that you do not have a usable clinical MRI, you may be required to undergo a research scan prior to the study. The MRI scanner is a large machine that contains a hollow tube. At each visit you will be asked to lie on your back on a special table that slides into the tube. The sides of the tube will be fairly close to your body and the scanner will make a loud hammering noise while you are inside. You will be required to wear earplugs during your scan to minimize the risk of hearing loss. You will be able to talk to the MRI technician through a speaker system. We will monitor you closely while you are inside the scanner. Sessions will be scheduled at your convenience and may contain different sequences lasting varying lengths of time. The total time spent in the scanner for each session will be at least 30 minutes but not more than 2 hours.

Audiological Assessment: We may ask you to listen to a series of tones and frequencies to better understand your tinnitus symptoms. This will involve wearing headphones and rating changes in tinnitus intensity while we play auditory tones.

Electroencephalography (EEG): We will attach EEG electrodes to your scalp that will record your brain activity before, during, and after TMS stimulation at your first visit. This involves the use of electrode gel and a special cap that you wear on your head. As a result, you may have some minor markings on your skin and your hair may be a bit messy or damp afterwards. The recording of brain activity is painless.

TMS: Before treatment, we will measure your motor evoked threshold to determine the intensity of stimulation to be used. This will involve placing of the TMS coil on the scalp over motor cortex and administering pulses while we observe movements in your hand. The TMS device uses electromagnetic induction to electrically stimulate the brain non-invasively from outside the head and is safe and commonly used clinically to treat major depressive disorder. Magnetic pulses generate a weak electrical current in the brain that briefly activates cortical neurons at the stimulation site. The strength of the magnetic fields produced is the same type of strength as those used in magnetic resonance (MRI) machines. We will ask that you wear a headband tracker that allows us to perform neuronavigated stimulations using an infrared camera and computer software. Treatment will consist of repetitive TMS (rTMS) trains at specific locations on the scalp.

Data Storage for Future Use

As part of this study, we are obtaining data from you. The contribution of your data for future use is mandatory for participation in this study.

The tests we might want to use to study your data may not even exist at this time. Therefore, we will store your data so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding human brain function, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your data might be used to develop products or tests that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.

Your data will be stored without your name or any other kind of link that would enable us to identify which sample(s) are yours. It will be available for use in future research studies indefinitely and cannot be removed.

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.

The most common side effect of TMS is scalp discomfort at the site of stimulation and muscle twitching in the region of stimulation. Other side effects that are uncommon include hearing loss (ear plugs are required), dental pain, or headache.

The most significant adverse event associated with TMS is inducing a seizure. This is a rare event for healthy participants but there will be a neurologist present during all TMS procedures.

WHAT ARE THE BENEFITS OF THIS STUDY?

There is some evidence that TMS can be used to treat chronic tinnitus. We will choose your stimulation protocol based on previous studies and current research. However, there is a good chance that you may not benefit from this study. We hope that, in the future, other people might benefit from this study because it could lead to new treatments.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

All study visits, procedures, and tests will be provided at no cost to you.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?

The University and the research team are receiving no payments from other agencies, organizations, or

companies to conduct this research study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

- If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.
- The University of Iowa does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a University employee.
- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that 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.

- federal government regulatory agencies,
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will store all information in a locked, password encrypted secure research drive that is s stored in a locked room. Your paper records will also be secured in a locked room. All data will be encrypted with study ID codes and coded data will be stored separately from identifying information. 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.

The University of Iowa Hospitals and Clinics generally requires that we document your participation in research occurring in a University of Iowa Health Care facility. This documentation will be in either your medical record or a database maintained on behalf of the institution reflecting that you are participating in this study. The information included will provide contact information for the research team as well as information about the risks associated with this study. We will keep this Informed Consent Document in our research files; it will not be placed in your medical record chart.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires University of Iowa Health Care to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study and your treatment. Once UIHC has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff, You cannot participate in this study unless you permit us to use your protected health information. If you choose not to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related. Your signature on this Consent Document authorizes to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to Aaron Boes, W278 GH, Iowa City, IA 52242 However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

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. 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 HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact Dr. Aaron Boes, (319) 353-8587. If you experience a research-related injury, please contact: Dr. Aaron Boes, (319) 353-8587.

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the

Human Subjects Office at the number above.

This Informed Consent Document 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 signing this Informed Consent Document. 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 copy of this form.

Subject's Name (printed): _____

Do not sign this form if today's date is on or after EXPIRATION DATE: 08/27/21.

_____ _____

(Signature of Subject) (Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent)