Letter of Information

1. Invitation to Participate

You are being invited to take part in this study investigating whether 10 consecutive sessions of repetitive transcranial magnetic stimulation (rTMS) is effective in improving long-term, bothersome tinnitus (also known as ringing in the ears).

2. Purpose of the Letter

This letter is meant to provide you with the information needed for you to make an informed choice about taking part in this research study.

3. Purpose of this Study

This study is being done to investigate whether rTMS is helpful in improving function, quality of life and symptom control in people with long-term, bothersome tinnitus.

At this time, there is a lack of good treatments for bothersome tinnitus. This study is expected to yield valuable information that may guide the use and adoption of rTMS as a treatment for people with tinnitus.

4. Inclusion Criteria

People with chronic, bothersome tinnitus (defined as a score of 32 or more on the Tinnitus Functional Index, and 38 or more on the Tinnitus Handicap Inventory) with or without a history of traumatic brain injury (TBI) can participate in this study.

5. Exclusion Criteria

People who have a known seizure disorder, a family history of epilepsy, are under age 18, are pregnant, have metal in their head, regularly consume alcohol, or who take certain medications (benzodiazepines, insulin, prednisone, immunosuppressants, narcotics, stimulants) are not eligible to take part in this study. People with tinnitus that
is not long-term and bothersome in nature will be excluded. As well, all patients with an underlying problem causing the tinnitus (e.g., Acoustic neuroma) will not be eligible.

6. **Study Procedures**

If you agree to take part, you will be asked to spend roughly 12 hours of your time over 12 sessions. At the start of the study, you will be asked to fill out tinnitus and hearing surveys, and to have a hearing test. You will then be asked to complete ten sessions of rTMS taking roughly one hour each day for ten consecutive business days. You will then be asked to fill out tinnitus and hearing surveys at the end of the ten rTMS sessions. Two months after completing the study, you will be asked to fill out the tinnitus and hearing surveys, and have a hearing test.

These tasks will occur at Hotel Dieu Hospital and Providence Care. There will be about 40 participants in this study.

Relevant information about your tinnitus will also be obtained from your paper and electronic medical charts.

7. **Possible Risks and Harms**

The main risks of this study are scalp irritation and headache after your rTMS sessions.

There is a very small chance (roughly 1 in 15,000 or 0.0067%) that you may have a seizure during, or after your rTMS session. A medical team including a physician and nurses will be on site at all times in case a medical complication were to arise.

8. **Possible Benefits**

Research suggests that rTMS has the potential to be highly effective in treating bothersome tinnitus. It is possible that taking part in this study will improve your tinnitus.

By taking part in this study, you are helping physicians and researchers to design better treatments for other people like yourself with bothersome tinnitus.

9. **Compensation**

You will not be compensated for taking part in this research.

10. **Voluntary Participation**
Participation in this study is voluntary. You may refuse to take part, refuse to answer any questions or withdraw from the study at any time with no effect on your future care.

11. Confidentiality

All data collected will remain confidential, will be stored in a locked office, and will be accessible only to the investigators of this study. If you choose to withdraw from this study, your data will be removed and destroyed. If the results are published, your name will not be used.

Representatives of the Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB) may contact you or require access to your information to monitor the conduct of this research.

12. Contacts for Further Information

If you require more information about this project or your participation in this study, please contact Dr. Jason Beyea (Principal Investigator) at (613) 544-3400 ext.3620 or beyeaj@kgh.kari.net

If you have any concerns about your rights as a research participant please contact - Dr. Albert Clark, Chair of the Queen's University Health Sciences and Affiliated Teaching Hospitals Health Sciences Research Ethics Board at (613) 533-6081 or clarkaf@queensu.ca

13. Publication

If the results of this study are published, none of your identifying or contact information will be used. If you would like to receive a copy of the study results, please provide your name and contact information on a piece of paper separate from the Consent Form.

14. Consent

Enrolment in this study is only with your written, informed consent. If this study has been explained to your satisfaction, and you would like to take part, please find the Consent Form attached.

This letter is yours to keep for future reference.


Consent Form

Project Title: Primary auditory cortex rTMS for patients with chronic, bothersome tinnitus in healthy patients and those with a history of traumatic brain injury.

Study Investigator’s Name: Jason A. Beyea, MD PhD FRCSC. Department of Otolaryngology, Queen’s University, Kingston, ON.

I have read the Letter of Information, have had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction.

Participant’s Name (please print): __________________________________________

Participant’s Signature: __________________________________________

Date: __________________________________________

Person Obtaining Informed Consent (please print): ___________________________

Signature: ___________________________

Date: ___________________________