Informed Consent Document

Official Title: Simultaneous Bilateral Radiofrequency Thalamotomy Targeting the Ventral Intermediate Nucleus for Medication-Refractory Essential Tremor: Informed Consent Document

NCT Number: [Pending NCT Number]

Document Date: July 03, 2025

Title: Simultaneous Bilateral Radiofrequency Thalamotomy Targeting the Ventral Intermediate Nucleus for Medication-Refractory Essential Tremor: Informed Consent Document

Version: 6

Date: April 8, 2025

Principal Investigator: Shiro Horisawa, MD

Affiliation: Department of Neurosurgery, Tokyo Women's Medical University

Dear Participant,

We invite you to participate in a clinical study entitled "Simultaneous Bilateral Radiofrequency Thalamotomy Targeting the Ventral Intermediate Nucleus for Medication-Refractory Essential Tremor." Please read this explanation carefully and decide of your own free will whether or not to participate. If you agree to participate, please sign the consent form provided.

About Clinical Research Clinical research is essential to develop and improve diagnostic and therapeutic methods. This study has been reviewed and approved by the Ethics Committee of Tokyo Women's Medical University and will be conducted with the permission of the university president.

Purpose and Significance of This Study Essential tremor is one of the most common involuntary movement disorders, affecting 2.5–10% of the population. When medications fail to control tremor, surgical options targeting the ventral intermediate nucleus (Vim) of the thalamus can provide significant relief. This study evaluates the safety and efficacy of simultaneous bilateral radiofrequency thalamotomy to control tremor in both hands without implanting a device.

About the Surgical Procedure High-frequency thalamotomy involves creating small thermal lesions in the Vim using a stereotactic electrode. The procedure begins on the dominant-hand contralateral side, followed by MRI to assess for hemorrhage. If no complications are seen, the opposite side is treated. If hemorrhage occurs, surgery ends after the first side.

Eligibility Criteria

Inclusion:

- Aged 20 to under 70 years
- Diagnosed with essential tremor by a movement disorder specialist
- Refractory to medications such as propranolol, alprenolol, primidone, or benzodiazepines
- Provided written informed consent

Exclusion:

- Contraindications to MRI
- Intracranial lesions interfering with surgery
- Cognitive decline
- Pregnancy
- Bleeding tendency

- Any condition deemed inappropriate by the investigator

Procedures and Timeline You will undergo MRI, tremor evaluation, quality of life (QUEST), ataxia (SARA), mood scales (BDI, BAI, AES), and cognitive testing (MMSE). Postoperatively, you will be evaluated at 1 week, 1 month, 3 months (including MRI), and 6 months.

Expected Benefits This procedure may relieve tremor in both hands without requiring device implantation. Your participation may contribute to improving treatment options for others.

Risks and Side Effects Possible complications include:

- Transient dysarthria (~10%)
- Dysphagia (~5%)
- Numbness or taste disturbance (~5%)
- Transient gait disturbance (~5%)
- Intracranial hemorrhage (<1%) These side effects are usually mild and often resolve over time.

Alternative Treatments Alternative options include medication, deep brain stimulation (DBS), or MR-guided focused ultrasound. Participation in this study is voluntary and refusal will not affect your standard of care.

Voluntary Participation and Withdrawal You may choose not to participate or withdraw at any time without penalty or disadvantage to your medical care.

Handling of Personal Information Your personal data will be anonymized and managed securely. Any data shared for research will be de-identified. Only authorized personnel and oversight bodies may review your records.

Compensation for Injury In the event of a health issue caused by study participation, necessary medical care will be provided. Serious adverse events caused by the study may be eligible for compensation through clinical trial insurance.

Cost and Funding You will bear standard medical expenses as covered by national health insurance. No additional payments or incentives will be provided.

Contact Information If you have any questions, please contact: Dr. Shiro Horisawa, Assistant Professor Department of Neurosurgery Tokyo Women’s Medical University Tel: +81-3-3353-8111

I have received sufficient explanation about this clinical study. I understand the content and voluntarily agree to participate. I also received a copy of this explanation and consent form.

Date (YYYY/MM/DD): _____

Participant Name (Signature): _____

For Future Data Use:

□ I agree / □ I do not agree to allow my data to be stored and used in future studies.

Investigator Signature

I have provided sufficient explanation and obtained consent from the above participant.

Date (YYYY/MM/DD): _____

Investigator Name (Signature): _____

Withdrawal of Consent Form

I hereby withdraw my consent to participate in the above study.

Date (YYYY/MM/DD): _____

Participant Name (Signature): _____

Confirmed by Investigator:

Date (YYYY/MM/DD): _____

Investigator Name (Signature): _____