PROJECT TITLE:

A Clinical Trial Evaluating the Efficacy of Combining Interstitial Thermal Ablation with and without Spine Stereotactic Radiosurgery for Patients with Spine Metastases

Protocol Version # and Date: V3, 05/24/2024

INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Principal Investigator (PI): Ian Lee, MD
PI Address: 2799 W. Grand Blvd., Detroit MI, Floor K11
PI Phone: (313) 916-2723

1. INTRODUCTION

You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when deciding whether or not to participate. More detailed information is provided in the body of the consent. No research activity is to be conducted until you have had an opportunity to review this consent form, ask any questions you may have, and sign this document.

REQUIRED

Key Information for You to Consider
Voluntary Consent. You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when making a decision whether or not to participate. More detailed information is provided after the box. No research activity is to be conducted until you have had an opportunity to review this consent form, ask any questions you may have, and sign this document. Participation is voluntary. There will be no penalty or loss of benefits if you choose not to participate or discontinue participation. **Purpose**. The purpose of this research is to combine two complementary modes of treatment, laser ablation and spinal radiosurgery. Together these may help the surgeon better treat the tumor close to your spinal cord with a goal of improving tumor control, pain control, preserving function, and increase quality of life. **Duration**. It is expected that your participation in this study will last two years. **Procedures and Activities**. You will undergo minimally invasive spinal surgery. You will have one inpatient stay in the hospital after your surgery. There will be a total of 10 outpatient visits lasting approximately 1 hour in duration. As a part of your participation,

you will complete a total of 10 sets of surveys to measure your quality of life for the duration of the study.

Risks. Some of the foreseeable risks or discomforts of your participation may include permanent damage to the spinal cord, nerves, and blood vessels.

Benefits. Some of the benefits that may be expected are that the surgery is less invasive and there is a decreased chance of prolonged hospital stay. Compared to standard surgical techniques, it may also be less risky. There is the overall benefit of tumor control.

Alternatives. As an alternative to participation, you could have an open surgery with no laser ablation or radiation. You can choose not to have any intervention

2. DISCLOSURE OF POTENTIAL CONFLICT OF INTEREST

The Henry Ford Health System (HFHS) investigator(s) on this study are also healthcare providers. They are interested in the knowledge to be gained from this study and are interested in your well-being. Investigators may obtain salary or other financial support for conducting the research.

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3. WHY IS THIS RESEARCH BEING DONE?

You have been asked to take part in a research study because you:

- You have been diagnosed with a tumor near your spinal cord.
- Treatment of your spinal tumor can be performed using percutaneous (through the skin) spinal tumor procedures that require imaging at Henry Ford Hospital.

A total of 15 people will be enrolled at Henry Ford Hospital (HFH).

The purpose of this research study is to combine two complementary modes of treatment, spinal interstitial laser ablation and stereotactic spine radiosurgery (SSRS) for the treatment for spinal tumors near the spinal cord with an objective to improve tumor control, improve pain control, preserve function, and improve quality of life. We will also assess how effective it is to use these two treatments together in patients who have spine metastasis.

4. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

Before you begin the study, your neurosurgeon will observe your tumor region along with other medical history in order to determine the appropriate treatment plan. After review of your medical history and study eligibility is confirmed, the study treatment plan will include the following:

During the Pretreatment phase, the following will take place:

- Baseline History and Physical exam including a detailed neurological assessment.
- Documentation of Steroid medication use and Pain Medications
- Magnetic Resonance Imaging (MRI) of the spine (with and without contrast) within 4 weeks of enrollment. With contrast a dye is injected into your blood vein. The contrast liquid circulates through the bloodstream and is absorbed in certain tissues, making them glow and stand out more on the scan.
- 3 Baseline Quality of Life surveys: Brief Pain Survey, Health Survey, Spine Symptom Survey
- You will need pre-authorization from your insurance company to participate in this study. If your insurance will not cover payment for the surgery, you will be removed from the study and treated off protocol.
- Radiation Treatment Simulation (within 3 weeks of enrollment) will determine the correct dose of radiation you are to receive.

During Treatment Phase, you will have the following procedures:

- Thermal ablation: This will be done in the intraoperative MRI suite, where you will receive general anesthesia and then positioned over gel like rolls. This will allow us to capture images. Our Intraoperative MRI is an MRI room that is placed next to our surgical suite. There is a door between the operating room and the MRI room. The MRI room was built to OR standards such has exchange of air flow, tiled walls and lighting.
- When the surgeon deems fit, the door will open, and the surgical bed will dock with the MRI table. The door between the operating room and the MRI room will close.
- Stereotactic Radiosurgery 1-14 days later: CT guided radiation therapy that will help deliver the treatments to the tumor tissue. This procedure allows us to treat the tumor tissue only and sparing any normal tissue nearby.
- The stereotactic needle will be placed to proceed with the laser ablation. During laser ablation, you will feel slight heat that is not painful and will not cause any tissue damage. The system has an automatic deactivation technique in place if the temperature reaches the highest, non-damaging tissue point.

During the Follow up Phase, you will have the following evaluations done at months 1, 3, 6, 9, 12, 18, 24; then yearly:

- History and Physical exam
- Documentation of Steroid medication use and Pain Medications
- Toxicity Check (what symptoms are you experiencing)
- The same 3 Quality of Life surveys about your Pain, Health, and Spine that you completed before surgery.
- Routine MRI scan (with and without contrast)

The follow up visit will continue annually after month 24. The doctor can arrange additional follow up visits at any time that may be off schedule. A Phone Call visit is required if you are ill and cannot physically make an office visit or if you have symptoms have progressed.

For some research studies, including the one you are being asked to join, you will be given the results of certain tests performed prior to or during your procedures. The physician will review these with you during your study related visits in order to determine the next steps of the treatment plan.

MRI Guided Laser Ablation Process:

You will be put under anesthesia (asleep) before the procedure starts and be placed in the prone position (facedown). An intraoperative CT scan of your vertebra (small bones which make up the backbone) will be used to create high resolution images. This will allow your neurosurgeon to properly direct the final placement of the laser probes to the intended targeted area.

You are then brought into the intraoperative MRI suite and placed into the MRI scanner where a scan is done to locate the exact coordinates of the laser fibers. The laser fibers will be turned on, and heat will destroy the tissue where the laser is located. The MRI scanner lets the surgeon see the tissue being heated up and destroyed in real-time. The tissue-heating part of the procedure takes a few minutes, and the whole process including the MRI scan takes several hours.

At the end of the procedure, you will be taken to the post-operative care unit to recover from the anesthesia. Then transferred to a regular room and discharged from the hospital within 24 hours.

SSRS Process:

Radiation treatment simulation: Before you begin your treatment, you will have a treatment planning procedure called **simulation**. A simulation is useful to verify the right treatment plan and to diagnose the extent of the surrounding tissues for proper selection of the size and orientation of the radiation beam. This is a practice run without actually giving radiation therapy. Your team will use imaging scans to identify the tumor location.

Radiation treatment: *Stereotactic Radiosurgery* is a type of radiation therapy that uses special equipment to position the patient and precisely give a single large dose of radiation to a tumor. It is not surgery in the traditional sense because there's no incision. Instead, stereotactic radiosurgery uses 3D imaging to target high doses of radiation to the affected area with minimal impact on the surrounding healthy tissue.

Surveys: These are tools to assess the impact of treatment on your quality of life. They will help the study team assess adverse side effects of these types of procedures. You will complete the surveys via MyChart prior to your visit or a hard copy of the survey will be provided for you at the time of your in-person appointment.

Administration of the surveys can take place one of two ways if you miss your in-person visit:

1) Epic MyChart - You will be notified via MyChart to complete the surveys prior to your scheduled appointment.

2) Paper Copy – Should an electronic device not be available at the time of our appointment; a paper copy of the surveys will be provided.

Completing the surveys will take approximately 10 minutes of your time.

5. WHAT ARE THE RISKS, DISCOMFORTS, OR INCONVENIENCES OF PARTICIPATING IN THE STUDY?

While you are in the study, you are at risk for the following side effects:

Likely (5%)
• Tumor Progression
Less Likely (Less than 5%)
• Spinal Cord Injury • Paralysis • Nerve Injury • Wound Infection or Abscess • Blood Vessel Injury
Rare but Serious (1%)
• Spine Fracture

The researchers will try to minimize these risks by ensuring accurate placement of the probe by placing proper landmarks on the skin of the participant. The surgeon judges accuracy before proceeding.

<u>Radiation Therapy Risks</u>

Reactions may include, but not necessarily limited to the following:

Likely Reactions to the treated area:

- Skin reddening & irritation.
- Occasional discomfort and sensitivity
- Occasional aches and pains

Less Likely: occurring in 1-5% of people treated.

- Skin blistering or peeling

Rare: occurring in less than 1% of people treated

- Painful ulceration and infection in the treated area
- Allergic reaction to contrast dye

BREACH OF CONFIDENTIALITY RISK: Additional risks include a potential breach of confidentiality of your personal information. The measures taken to protect your personal information and any possible disclosure are described in the section below titled "*How will my personal information be protected*?"

BLOOD DRAW RISK: Blood samples will be obtained from your veins. Possible side effects of obtaining blood samples are pain, bruising, bleeding, or infection at the blood draw site. Occasionally nausea, lightheadedness or fainting may occur.

The researchers will try to minimize these risks by reviewing your signs and symptoms with you as it relates to reactions to the procedures and monitoring data on a regular basis.

There may be additional risks or discomforts that are not known at this time.

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study. If you are currently in another study, took part in one recently, or if you consider another study in the future, please inform the research staff right away.

IF WOMEN OF REPRODUCTIVE CAPACITY ARE PERMITTED IN THE STUDY AND THE DRUG HAS POTENTIAL RISK TO THE FETUS:

Pregnancy Risks

There could be risks to you or your unborn child that the investigators cannot predict. If you are a woman who is capable of becoming pregnant, we ask that you take precautions by using contraceptives during the time of this surgical treatment. Please to your study doctors if you should become pregnant before or during active treatment.

6. WHAT ARE THE BENEFITS TO TAKING PART IN THE STUDY?

Due to the minimally invasive nature of the surgery compared to traditional open surgery, the benefits of participating in this study may include lower risk of infection or bleeding, shorter recovery and less time in the hospital. It will also help researchers discover more effective ways to treat tumors near the spinal cord.

7. WHAT OTHER OPTIONS ARE THERE AND WHAT ARE MY ALTERNATIVES?

Your participation is voluntary. You do not have to participate in this study. The alternative to participating in this study is to have an open surgical removal of spinal tumor without the use of laser

ablation technology, having radiation treatment alone, or not having any intervention. You should speak with your doctor to discuss all possible options before making your decision.

Talk to your doctor and family about your choices before you decide if you will take part in this study.

8. HOW WILL MY PERSONAL INFORMATION BE PROTECTED?

Your identifiable private information or identifiable biospecimen, even if stripped of identifiers, will not be used for future research studies, or distributed to another researcher for future research studies without additional informed consent.

You should also know that the HFHS Institutional Review Board (IRB) and IRB Administration Office may inspect study records as part of its auditing program, but these reviews only focus on the researchers. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

To the extent allowed by law, every effort will be made to keep your personal information confidential. However, information from this study will be submitted to the FDA. It may be submitted to governmental agencies in other countries where the study device may be considered for approval. Medical records, which identify you and the consent form signed by you, will be looked at by the Sponsor or the Sponsor's representatives and may be looked at by the FDA and other regulatory agencies. Your study data will be kept on file indefinitely.

You should also know that the HFH Institutional Review Board (IRB) and IRB Administration Office may inspect study records as part of its auditing program, but these reviews only focus on the researchers. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

Future Research

Your identifiable private information or identifiable biospecimens may be stripped personal health information and deidentified. Your data will not be used for future research studies or distributed to another researcher for future research studies without your additional informed consent.

Your identifiable private information or identifiable biospecimen, even if stripped of identifiers, will not be used for future research studies or distributed to another researcher for future research studies without additional informed consent.

9. WHAT IF I GET SICK OR I AM INJURED?

There is no federal, state, or other program that will compensate you or pay for your medical care if you are injured as a result of participating in this study. You and/or your medical insurance may have to pay for your medical care if you are injured as a result of participating in this study.

By signing this consent form, you do not give up any of your legal rights in the event of an injury.

10. WHO DO I CONTACT WITH QUESTIONS ABOUT THE STUDY OR TO REPORT AN INJURY?

Dr. Ian Lee, MD, or his/her staff member has explained this research study and has offered to answer any questions. If you have any additional questions about the study procedures, or to report an injury you may contact Dr. Ian Lee by phone at (313) 916-2723 or by email at ilee1@hfhs.org. Medical treatment is available to you in case of an injury.

If you would like to discuss your rights as a research participant, report problems or concerns, ask questions, obtain additional information, or offer input with an informed individual who is unaffiliated with the research study, you may contact the Henry Ford Health IRB Administration Office by phone at (313) 874-4464 or by email at irbquestions@hfhs.org.

11. DO I HAVE TO PARTICIPATE IN THIS STUDY?

You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. Inform the research staff/study doctor if you are thinking about stopping or decide to stop. There are no penalties or loss of benefits to which you are otherwise entitled if you decide that you do not want to participate.

If choose to stop participating, you may be asked to return for a visit for safety reasons. You will get the same medical care from HFH whether or not you participate in this study. You will be told about any significant information that is discovered that could reasonably affect your willingness to continue being in the study. You will be notified of all significant new findings during the course of the study that may affect your willingness to continue.

WHO ELSE CAN STOP MY PARTICIPATION?

The study doctor (Drs. Lee or Robin) can end your participation in the research study without your approval if there are increased risks or other study concerns. In the post-operative monitoring period, it's possible that that you could have a fracture, worsening imaging, and/or increased weakness or pain which would result in a need for further surgery. In that case, you would remain on study to monitor your outcome. However, possible reasons for removal from the study are mostly due to technical factors surrounding the laser procedure, which include, but are not limited to:

1. Inability to place the laser fibers safely or accurately;
2. Body size or shape which would not allow the patient to be placed in the MRI scanner;
3. Inability to obtain necessary intraoperative imaging to perform the procedure.

If this is necessary, your doctor will discuss it in detail with you. You may be asked to return for a final visit for safety reasons.

12. WILL IT COST ANYTHING TO PARTICIPATE?

The reference array used to place the laser fibers during surgery is supplied by a company called BrainLAB and will not be charged to you. There may also be other procedures, and study visits that will be provided at no charge.

You will still be responsible for the cost of your usual ongoing medical care, including procedures and drugs that are not required by this study.

While some of the tests and exams may be considered standard of care, they may or may not be covered by your medical insurance. You may be responsible for insurance co-payments. If your medical insurance does not pay for your care, you may be responsible for the cost of the medical care related to your condition including but not limited to laboratory tests, deductibles, co-payments, physician and clinic fees, hospitalization, and procedures.

If you have any questions about the costs of this study, please ask the study doctor, or a member of the study staff.

Additional costs may include <insert specific costs. Be sure to include any co-pays, transportation costs, including lodging, travel, parking, etc.> You have the right to ask what it will cost you to take part in this study. If you have any questions about the costs of this study, please ask the study doctor, a member of the study staff, and/or your health care provider.

IF THERE ARE NO EXTRA MEDICAL COSTS, OR IF ALL OF THE COSTS (INCLUDING THOSE RELATED TO RESEARCH INJURIES AND INSURANCE-RELATED) WILL BE BORNE BY THE STUDY SPONSORING/FUNDING AGENCY: There will be no charge to you for your participation in this study. The <investigational drug/device, study-related procedures, and study visits> will be provided at no charge. You will still be responsible for the cost of your usual ongoing medical care, including <procedures and drugs that are not required by this study>. You have the right to ask what it will cost you to take part in this study. If you have any questions about the costs of this study, please ask the study doctor, or a member of the study staff.

The sponsor and/or Henry Ford Health will pay for the tests and examinations that are required by this study and anything else that is not part of your standard medical care. While some of the tests and exams may be considered standard of care, they may or may not be covered by your medical insurance. You may be responsible for insurance co-payments. If your medical insurance does not pay for your care, you may be responsible for the cost of the medical care related to your condition including but not limited to laboratory tests, deductibles, co-payments, physician and clinic fees, hospitalization, and procedures.

13. WILL I BE PAID TO PARTICIPATE?

There is no compensation being offered for your participation in this study.

DOCUMENTATION OF CONSENT

By signing this form, I agree that I have read and understand this form and that I agree to participate in the research project described above. I have been given enough time and opportunity to ask about the details of the research study and to decide whether or not to participate. Its general purposes, the particulars of my involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time without giving any reason, without my medical care or legal rights being affected. My signature also indicates that I have received a copy of this consent form.

The researchers in this study might want to ask you to participate in additional studies. In some cases, you might be a good candidate for a particular study because of your health history or genetic information.

I am willing to be contacted for participation in future research studies. Please initial below.

_____ I agree

_____ I refuse

Signature of Participant	Date	Time
Printed Name of Participant		
Signature of Witness to Consent*	Date	Time
Printed Name of Witness*		

**Use in cases when the consent form has been read to the participant (e.g., legally blind, illiterate, Non-English speaking, etc.) or when they are unable to provide a signature due to physical limitations)*

Signature of Person Obtaining Consent	Date	Time
Printed Name of Person Obtaining Consent		

INFORMATION ABOUT CONFIDENTIALITY AND HIPAA AUTHORIZATION

A federal regulation, known as the Health Insurance Portability and Accountability Act (HIPAA) gives you certain rights concerning the use and disclosure (sharing with others) of your Protected Health Information (PHI). This regulation provides safeguards for the privacy and security of your information. Your permission (authorization) is required for the use and sharing of any PHI collected as part of this research study. If you are not willing to sign this authorization to use and/or disclose your PHI by the research team, you will not be eligible to take part in this research study.

The Principal Investigator (PI) and his research team will use your medical records and information created or collected as part of this research study. Your PHI is important for the PI and his research team to collect information about you during the study, to be able to contact you if needed, and to provide treatments to you during the study, if required. The PI may send out your study related health information to the sponsor or other entities involved in this study.

We will collect and use:

- Name.
- Date of Birth.
- Medical Record Number.
- Demographic information.
- Test results.
- Medical history.
- Diagnostic and medical procedures

We may release this information to the following people:

- The Principal Investigator and his/her associates who work on or oversee the research activities.
- Henry Ford Health Institutional Review Boards (IRB)
- Government agencies and officials who oversee research (e.g., FDA, OHRP, OCR, etc.).
- The device sponsors, Medtronics and Brain Lab
- Your insurance company or others responsible for paying your medical bills.

Once your information has been released according to this Authorization, it could be released again and may no longer be protected by federal privacy (i.e., HIPAA) regulations.

This Authorization, any test results, medical reports, and other information about you from this study may be placed into your medical record. Generally, you are allowed to look at your medical record. During the research study, you will not be allowed to look at the research study information that is not in your medical record.

No names, identifying pictures or other direct identifiers will be used in any public presentation or publication about this study unless you sign a separate consent allowing that use.

This Authorization to use and release your personal protected health information does not expire.

You do not have to sign this Authorization and may cancel it at any time. If you decide to cancel your Authorization at a later date, you will not be able to continue to participate in this study. If you withdraw your permission, we may continue to use and release the information that has already been collected. To cancel your consent, send a written and dated notice to the following:

Ian Lee, MD
Henry Ford Hospital
2799 W. Grand Blvd
Department of Neurosurgery – Desk K11
Detroit, MI 48202

By signing this document, you are authorizing the PI to use and disclose PHI collected about you for the research purposes as described above.

Signature of Participant	Date	Time

Printed Name of Participant