



## Informed Consent

### INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Radiofrequency Ablation Use in Thyroid Nodule  
2021-0542

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Study Chair: Kim Learned, MD

\_\_\_\_\_  
Participant's Name

\_\_\_\_\_  
Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This research has been reviewed and approved by an Institutional Review Board (IRB - a committee that reviews research studies).

#### **STUDY SUMMARY**

The goal of this research study is to learn if ultrasound-guided radiofrequency ablation (RFA) can provide the same treatment result as standard surgical resection of the thyroid nodule, small primary thyroid, or recurrent thyroid cancers. Researchers also want to learn if the procedure can be less invasive and perhaps provide a better recovery response than surgery.

#### **This study is investigational.**

Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including potential expenses and time commitment.

You can read a list of potential risks below in the Possible Risks section of this consent.

Your participation in this study will be over after your follow-up visit (6-12 months after you have an RFA).

You and your insurance provided will be responsible for the ultrasound-guided radiofrequency ablation (RFA) procedure.

Instead of being in this research study, your choices may include: **surgery to remove the thyroid nodule/lesion or active surveillance**. These alternative treatments have risks and benefits that may be the same or different than those in this research study. The study doctor can discuss these alternative treatments, including their risks and benefits, with you. You may choose not to take part in this study.

## 1. STUDY DETAILS

### **Screening Tests**

Signing this consent form does not mean that you will be able to take part in this study. The following screening tests will help the doctor decide if you are eligible:

- You will have a physical exam, including a skin exam.
- You will have an ultrasound to check the status of the disease.
- You will have a biopsy to confirm the status of the disease. To do this, a sample of tissue is removed using a needle.
- You will have a laryngoscopy to examine your throat. To do this, a camera will be passed through your nose and/or mouth. This will be performed by a head and neck surgeon and/or a speech language pathologist.
- Blood (about 2-4 teaspoons) will be drawn for routine tests.
- If you can become pregnant, this will include a pregnancy test. To take part in this study, you must not be pregnant.

The study doctor will discuss the screening test results with you. If the screening tests show that you are not eligible to take part in the study, you will not be enrolled. Other treatment options will be discussed with you.

Up to 100 participants will be enrolled in this study. All will take part at MD Anderson.

### **Study Procedure**

If you are found to be eligible to take part in this study, you will have thyroid RFA. During this procedure, a small needle electrode is inserted into the thyroid nodule using ultrasound guidance. Heat generated at the needle tip destroys the target tissue. The procedure typically lasts about 1-2 hours, depending on the size of the nodule being treated. You will leave the procedure suite the same day with only a small bandage. If you require any additional imaging, it will be done outside of this study.

### **Study Visits**

**On the day of the RFA procedure**, you will have a physical exam, including a skin exam.

### **Follow-Up**

You will have a routine thyroid follow-up visit at about 6-12 months after the

procedure. At this visit:

- You will have an ultrasound to check the status of the disease.
- You will have a physical exam.
- Blood (about 2-4 teaspoons) will be drawn for routine tests.

## 2. POSSIBLE RISKS

While on this study, you are at risk for side effects. These side effects will vary from person to person. The more commonly occurring side effects are listed in this form, as are rare but serious side effects. You should discuss these with the study doctor. You may also want to ask about uncommon side effects that have been observed in small numbers of patients but are not listed in this form. Many side effects go away shortly after the procedure, but in some cases side effects may be serious, long-lasting or permanent, and may even result in hospitalization and/or death.

Tell the study staff about any side effects you may have, even if you do not think they are related to the procedure.

**Radiofrequency ablation** may cause damage to the structures around the thyroid gland (skin, nerve, airway, and esophagus), hoarseness, nodule rupture, bleeding, infection that may require surgical treatment, pain, and discomfort. It may also cause underactive thyroid gland (possible weight gain, heart failure, and/or constipation).

**Blood draws** may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

Having **biopsies** performed may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the biopsies. An allergic reaction to the anesthetic may occur. A scar may form at the biopsy site.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

The procedure may involve unpredictable risks to the participants, including stroke and death.

## 3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. You may also

contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

Samples that are collected from you in this study may be used for the development of treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study.

### **Additional Information**

4. You may ask the study chair (Dr. Kim Learned, at 281-224-6455) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.
5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you withdraw from this study, you can still choose to be treated at MD Anderson.

If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can continue to collect data from your routine medical care. If you agree, this data will be handled the same as research data.

6. This study or your participation in it may be changed or stopped at any time by the study chair or the IRB of MD Anderson.
7. You will be informed of the results of all of your standard tests performed as part of this research.

8. MD Anderson may benefit from your participation and/or what is learned in this study.

### **Future Research**

#### **Data**

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and/or shared with other researchers and/or institutions for use in future research.

#### **Samples**

Samples (such as blood and/or tissue) are being collected from you as part of this study. Researchers at MD Anderson may use any leftover samples that are stored at MD Anderson in future research.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data and/or research samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or research samples are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or research samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

If you do not want your samples or data to be used for future research, tell the study doctor. You may withdraw your samples at any time by telling your study team. If you decide to withdraw your samples, they will be returned to the lab they came from or destroyed. However, the data and test results already collected from your samples will be kept and may be used.

### **Authorization for Use and Disclosure of Protected Health Information (PHI):**

- A. During the course of this study, MD Anderson will be collecting and using PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety related reasons, your doctor and the research team may share your PHI with:
- Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
  - The IRB and officials of MD Anderson

- Study monitors and auditors who verify the accuracy of the information
- Individuals who put all the study information together in report form

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

- B. Signing this consent and authorization form is optional but you cannot take part in this study if you do not agree and sign.
- C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

- D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer of MD Anderson at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

**CONSENT/AUTHORIZATION**

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

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SIGNATURE OF PARTICIPANT

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DATE

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PRINTED NAME OF PARTICIPANT**PERSON OBTAINING CONSENT**

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

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PERSON OBTAINING CONSENT

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DATE

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PRINTED NAME OF PERSON OBTAINING CONSENT

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**TRANSLATOR**

I have translated the above informed consent as written (without additions or subtractions) into \_\_\_\_\_ and assisted the people

(Name of Language)

obtaining and providing consent by translating all questions and responses during the consent process for this participant.

\_\_\_\_\_  
NAME OF TRANSLATOR

\_\_\_\_\_  
SIGNATURE OF TRANSLATOR

\_\_\_\_\_  
DATE



\_\_\_\_\_  
SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION  
(OTHER THAN TRANSLATOR, PARENT/GUARDIAN,  
OR STUDY CHAIR)

\_\_\_\_\_  
DATE

\_\_\_\_\_  
PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION