INFORMED CONSENT FOR CLINICAL RESEARCH

Predictive MRI metrics for tumor aggressiveness in papillary thyroid cancer

Patient Consent

You have been asked to participate in a research study. In order to decide whether or not you should agree to be part of this research study, you should know enough about its risks and benefits in order to make a sound judgment. This process is known as informed consent.

A member of the study staff will explain the research study to you. Research studies include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your family and friends.

This consent form gives you detailed information about the research study. Once you understand the study, its risks, and its benefits, you will be asked to sign the form if you wish to take part. You will be given a copy to keep.

Why is this study being done?

Magnetic resonance imaging (MRI) is a diagnostic technique that takes pictures of organs of the body. It uses magnetic fields and radio waves that cannot be felt. Perfusion MRI uses faster imaging. It also includes a contrast material that is given by vein. This makes specific organs, blood vessels, or tumors easier to see. Diffusion MRI lets us measure the motion of water in the tumor.

Perfusion and diffusion MRI give extra information which is not available with the regular MRI. A regular MRI only shows pictures of the tumor.

Thyroid MRI scans are not part of the current standard of care. The purpose of this study is to see if new MRI methods can give us more information about the tumor.

Is there a potential conflict of interest for this study?

There are no known investigator and/or institutional conflicts of interest for this study.

How was I selected to be in this study?

You are being asked to take part in this study because you have known or suspected papillary thyroid cancer.

How many people will take part in the study?

About 150 patients will take part in this study at MSKCC.

What will happen if I take part in this research study?

For an MRI test, the area of the body being studied is placed inside a special machine that contains a strong magnet. There may be some noise when images (pictures) are being taken and if you need you can be provided with ear plugs. A technician will give you instructions and can hear you in the MRI. If you agree and are eligible for the perfusion MRI, pictures will be taken before and after the contrast material is given. The diffusion MRI part is done before the perfusion MRI. The entire process, including setup, will take approximately one hour. The images are stored and viewed by the doctors.

The alternative to participating in this study is to not participate or to seek other studies. If you chose not to take part in this study you will continue to receive the same standard of care ordered by your physician.

We hope that what we learn from this study will benefit cancer patients, but we cannot say that it will help you directly. You may benefit from knowing that this research may help others.

Before you begin the study …

- We will ensure your eligibility for the study.
- You will fill out the patient consent form and a questionnaire

During the study…

If you choose to take part, then you will be asked to do the following:

- Stay in the MRI scanner for approximately 40 minutes

After the study…

After you are finished with the study, you will continue to be treated by your primary physician.

How long will I be in the study?

If you will be receiving surgery: you will be asked to take part in the study for the one MRI scan.

If you will be on active surveillance: you will be asked to take part in the study for the MRI scan and an additional MRI a year later.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest; if you do not follow the study rules; or if the study is stopped.

What side effects or risks can I expect from being in the study?

There are minimal side effects from perfusion and diffusion MRI. If you have a small medical device like a pacemaker or aneurysm clips, they could pose a risk to you and you would be excluded from this study. If you are sensitive to noise or have a disorder of the body's nervous system, you may have a hard time tolerating the MRI noise. Therefore it is recommended you talk to your doctor regarding the noise of the MRI before taking part in the study. There are no known side effects to them other than some patients feeling claustrophobic (fear of enclosed spaces) while inside the MRI machine.

The contrast material that is intravenously injected for use in perfusion MRI is also very safe. There are rare cases of nausea, headache, hives, temporary low blood pressure, allergic reactions, damage to the kidneys, and nephrogenic systemic fibrosis from the contrast material.

You should talk to your study doctor about any side effects that you have while taking part in the study.

For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?

The pictures and other data will be given to your doctors but will not affect the treatment being given to you by your doctor. There may be benefit for cancer patients in the future as more is learned about this new method.

Will I receive the results from the study?

No, you will not receive the results from this study because they do not effect your clinical management.

Do I have to take part in this study?

The choice to take part in this study or not is yours. Make your choice based on what we have explained to you and what you have read about the study

Will my medical information be kept private?

Every effort will be made to keep your study records private. It is the responsibility of the research staff at Memorial Hospital to make sure that your records are managed to protect your privacy. If information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. Trained staff at Memorial Hospital may review your records if necessary. Access to your medical information will be limited to those listed in the Research Authorization Form, which is a part of the informed consent process.

A description of this clinical trial may be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What are the costs of taking part in this study?

You and/or your health plan/ insurance company will need to pay for some or all of the costs of treating your cancer in this study. Some health plans will not pay these costs for people taking part in studies. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

You will not be charged for the entire study MRI to be performed.

You will not be paid for being part of the study.

What happens if I am injured because I took part in this study?

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for the medical treatment.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to the study principal investigator or your doctor about any questions or concerns you have about this study. Contact your doctor or principal investigator Amita Dave, PhD at (212) 639-3184.

Any hospital that does research on people has an institutional review board (IRB). This board reviews all new studies to make sure that the patient's rights and welfare are protected. The IRB at MSKCC has reviewed this study.

For a non-physician whom you may call for more information about the consent process, research patients' rights, or research related injury is Jorge Capote, RN, Patient Representative, telephone number: (212) 639-8254.

RESEARCH AUTHORIZATION

Predictive MRI metrics for tumor aggressiveness in papillary thyroid cancer

Research Participant Name: _____

Research Participant MRN :_____

Information about you and your health is personal. It is "Protected Health Information." We cannot use any of your health information for research unless you tell us that we can. If you take part in this research, the people or organizations that can look at your information are listed below. You will have to sign this form to tell us we have your permission to share your protected health information.

The following persons and/or organizations may use or disclose your information for purposes related to this research:

- The people in charge of the study and their assistants and support staff.

The following persons and/or organizations may look at your information for purposes related to this research:

- Members and staff of the hospital's Office of Clinical Research, Computing Resource Group that manages research databases, Data Safety Monitoring Board, and the Quality Assurance Committee.
- Members and staff of the hospital's Institutional Review Board and Privacy Board.
- The National Cancer Institute, National Institutes of Health, U.S. Food and Drug Administration, and other agencies responsible for oversight.
- The following sponsor(s) of this research: Memorial Sloan-Kettering Cancer Center

The following information will be used and/or disclosed for this research:

- Your entire research record.
- HIV-related information. This includes any information showing that you had an HIV-related test, have HIV infection, HIV-related illnesses or AIDS, or any information that could mean you might have been exposed to HIV. New York State requires us to obtain this consent.
- HIV-related information collected during this study if you choose to disclose it when talking to any of the staff.
- Your medical records from the hospital
- The following information: DCE-MRI and DW-MRI data

If you sign this form, it means you are giving us permission to share your protected health information. We can only share it with the people or organizations describe above. The purpose for the use and sharing of this information is to conduct this study. This signed form allows us to make sure that everyone who needs information related to this study can get it.

Your protected health information may also be used for your research treatment, to collect payment for care you receive while on the study (when applicable), and to run the business operations of the hospital.

Some of the people or organizations listed above may not be subject to privacy laws. This means they could share your information again.

You do not have to sign this form. If you do not sign it, you will not be able to take part in the study. Your health care outside the study will not be affected. The payment for your health care or your health benefits will not be affected.

You have the right to withdraw from the study at any time. If you sign this authorization form, you also the right to withdraw it at any time. If you withdraw it, we cannot use or share anymore of your research data. If the hospital has already used or shared your information, it cannot be taken back. This authorization allows us to use your information until you say we cannot use it anymore. If you want to withdraw your authorization, write to: Amita Dave at the Department of Medical Physics Memorial Sloan-Kettering Cancer Center.

Notice About HIV-Related Information

Once we have shared your HIV-related information, it can only be shared again if federal or state laws allow it. You have the right to ask for a list of any people who get your HIV-related information that are not listed above. There are two agencies to help protect your rights. Call them if you think you have been singled out or harmed because of HIV-related information.

- New York State Division of Human Rights (888) 392-3644
- New York City Commission of Human Rights (212) 306-7500

Please read the sentence below and check "Yes" or "No".

If you have any questions, please talk to your doctor or nurse. No matter what you decide to do, it will not affect your care.

1. I would like to participate in the perfusion MRI (MRI with contrast) part of the study.

☐ **YES**

☐ **NO**

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Statement of professional obtaining consent

I have fully explained this clinical research study to the participant or his/her Legally Authorized Representative (**LAR**). In my judgment and the participant's or that of his/her Legally Authorized Representative, there was sufficient access to information, including risks and benefits to make an informed decision.

Consenting Professional Must Personally Sign & Date		
Assent (Minor between the ages of 7 and less than 18): If the participant is a minor, I have obtained his/her assent to participate in the study to the best of their ability to understand. ☐ **YES** ☐ **NO** ☐ **N/A (Adult or Child <7)**		
Consenting Professional's Signature		**Date:**
Consenting Professional's Name (Print)		

Participant's (or Legally Authorized Representative's (LAR)) statement

I have read this form with the description of the clinical research study. I have also talked it over with the consenting professional to my satisfaction. By signing below, I am agreeing to the following: (1) to voluntarily be a participant in this clinical research study (2) authorizing for the use and disclosure of my/their protected health information (data about myself) and (3) that I received a signed copy of this consent form.

Participant/LAR Must Personally Sign & Date		
Participant/LAR Signature		**Date:**
Participant/LAR Name (Print)		
LAR Relationship to Participant		

Witness Signature (If Required)

☐ **Non-English Speaking Participant Witness and/or Interpreter:** I declare that I am fluent in both English and participant's (or LAR) language and confirm that the consent discussion was appropriately translated for the participant (or LAR).

☐ **Other:** I confirm that the consent discussion was appropriate for the participant's (or LAR's) understanding of the study.

Name of Witness: _____

Signature of Witness: _____ Date: _____

The Participant/Legally Authorized Representative Must Be Provided With A Signed Copy Of This Form.