PATIENT INFORMED CONSENT FOR CLINICAL RESEARCH

Dynamic Contrast Enhanced MRI (DCE-MRI) , Diffusion Weighted MRI (DW-MRI) and Magnetic Resonance Spectroscopy (MRS) of Head and Neck Tumors

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.

Your study doctor 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 friends and family. You can also discuss it with your healthcare team. If you have any questions, you can ask your study doctor for more explanation.

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.

You are being asked to take part in this study because you have head and neck cancer that will be treated with chemo-radiation or you have tumors strongly suspicious for head and neck cancer due to clinical features or FNA (fine needle aspiration) cytology assessment.

Why is this study being done?

Magnetic resonance imaging (MRI) is a diagnostic study that makes pictures of organs of the body using magnetic field and radio frequency pulses that can not be felt. Dynamic contrast enhanced–magnetic resonance imaging (DCE-MRI) uses faster imaging and contrast material (a substance used to make specific organs, blood vessels, or tumors easier to see) that is given by vein. Diffusion weighted magnetic resonance imaging (DW-MRI) allows to measure the motion of water around the cells in the tumor. Proton magnetic resonance spectroscopy (MRS) obtains chemical information from the tumor. During MRS, signals are detected from the chemicals (spectroscopy) naturally present in your tumor using radio waves. DCE-MRI, DW-MRI and MRS give extra information which is not available with the regular MRI. The regular MRI only shows pictures of the tumor while the DCE-MRI also gives information about the blood vessels of the tumor, DW-MRI provides information related to the state of the tumor tissue with regards to the quality or condition of cells present in it and MRS gives information about the chemical makeup of the tumor.

The purpose of this study is to see whether DCE-MRI, DW-MRI and/or MRS done before treatment can predict which patients will do well with either surgery or chemo-radiation therapy. This study will also see if DCE-MRI, DW-MRI and/or MRS done early in treatment can tell if the therapy is working.

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 many people will take part in the study?

About 335 people will take part in this study at Memorial Sloan-Kettering Cancer Center.

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

At MSKCC, patients with head and neck tumors usually have one regular MRI before either surgery or chemo-radiation treatment. For this study, you will have a regular MRI and a DCE-MRI, DW-MRI and/or MRS before

you start your treatment (pretreatment exam). If before coming to MSKCC, you already had a regular MRI done without the contrast material and fast imaging method, you will only have the DCE-MRI, DW-MRI and/or MRS parts of the study.

When you have the DCE-MRI, pictures will be taken before and after the contrast material is given. DW-MRI part is done before the DCE-MRI. The MRS part is done after the DCE-MRI and takes more pictures that show the chemistry of the tumor. The pretreatment DCE-MRI will add 10 minutes scanning time, DW-MRI will add 5 minutes and the MRS will add about 10 minutes scanning time as well, to the routine MRI study. If you do not need to have the regular MRI, the DCE-MRI, DW-MRI and/or MRS exam will take about 30-35 minutes (DCE-MRI about 10 minutes, DW-MRI about 5 minutes, and/or MRS about 10 minutes and setup on the MRI table will require 10-15 minutes).

Additional weekly DW-MRI studies will be performed during the course of treatment and will take approximately 15 minutes and two recommended DCE-MRI (unless contraindicated) will be performed when possible. The first intra-treatment DCE-MRI is recommended between the first and second weeks of treatment. The second DCE-MRI is recommended between the third and fourth weeks of treatment.
The DCE-MRI, DW-MRI and MRS studies will be done in the scanners located in the Department of Radiation Oncology at 1275 York Avenue.

When I am finished with the DCE-MRI, DW-MRI and MRS exams…

After completing the DCE-MRI ,DW-MRI and/or MRS exams, you will continue to be treated by your primary physician.

How long will I be in the study?

You will be asked to take part in this study until you have completed:

- DCE-MRI, DW-MRI and/or MRS exam (pretreatment). Some patients may receive a second DW-MRI right after the DCE-MRI if they agree to it. This would add less than 5 minutes to the scan. This will help us make the test more accurate for future patients.
- Weekly DW-MRI studies while undergoing chemo-radiation treatment
- Two recommended DCE-MRI (unless contraindicated). One between the first and second weeks of treatment and one between the third and fourth weeks.

We will clinically follow you for two years after you complete the DCE-MRI, DW-MRI and/or MRS exams and your planned treatment by reviewing your medical records. Checking on your records for these two years will help us to determine if pretreatment DCE-MRI, DW-MRI and MRS is able to predict which patients with head and neck cancer do well with either surgery or chemo-radiation treatment.

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?

DCE-MRI, DW-MRI and MRS are very safe tools and do not use radiation. 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 used in DCE-MRI is also very safe. There are rare cases of headache, itching, or rash 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?

Any DCE-MRI , DW-MRI and MRS 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.

What other choices do I have if I do not take part in this study?

Your other choices may include:

- Getting treatment or care for your cancer without being in a study
- Taking part in another study

Talk to your doctor about your choices before you decide if you will take part in this 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 will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. 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.

If you have not had previous MRI imaging, you or your insurance company will be charged for the routine pretreatment staging MRI as part of your care. If you have had an adequate pretreatment regular MRI from outside, then only the DCE-MRI**,** DW-MRI and MRS parts of the study will be performed and you will not be charged for it.

You will not be charged for the weekly DW-MRI after starting chemo-radiation therapy or for the two DCE-MRI scans that may take place during treatment.

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 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 your study doctor about any questions or concerns you have about this study. Contact one of the study doctors Amita Dave, PhD at 212-639-3184 or the study RSA, Christian Czmielewski at 212-639-2955.

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.

Dynamic Contrast Enhanced MRI (DCE-MRI) , Diffusion Weighted MRI (DW-MRI) and Magnetic Resonance Spectroscopy (MRS) of Head and Neck Tumors

Please read the sentence below and think about your choice.

After reading 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 diffusion repeatability MRI part of the study.	☐ **YES**	☐ **NO**

RESEARCH AUTHORIZATION

Dynamic Contrast Enhanced MRI (DCE-MRI), Diffusion Weighted MRI (DW-MRI) and Magnetic Resonance Spectroscopy (MRS) of Head and Neck Tumors

Research Participant **Name:** _____

Research Participant **MRN :** _____

We understand that information about you and your health is personal. We are committed to protecting the privacy of your information. Because of this commitment, we must obtain approval from you before we can use your protected health information for research purposes. This form provides that authorization. This form also helps us make sure that you are informed of how this information will be used or disclosed in the future. Please read the information below carefully before signing this form.

USE AND DISCLOSURE COVERED BY THIS AUTHORIZATION

A representative of Memorial Sloan-Kettering Cancer Center must answer these questions completely before providing this authorization form to you. ***PLEASE DO NOT SIGN A BLANK FORM.*** *You or your personal representative should read the descriptions below before signing this form.*

Who will have access to and/or use your health information?

The following individuals and/or organization(s) may have access to use, disclose or receive some information about you. They may only share the information to the individuals/parties indicated on this list. This information must be shared with you, the research subject and/or your personal representative, as required by law.

- Every research site for this study, including Memorial Sloan-Kettering Cancer Center and the research support staff (for example, research study assistant) and medical staff at each location
- Every health care personnel who provides services to you in connection with this study
- Any laboratories, other individuals/organizations that analyze your health information in connection with this study as defined by protocol
- The following research sponsor: Memorial Sloan-Kettering Cancer Center
- The National Institute of Health and the National Cancer Institute
- The United States Food and Drug Administration and other regulatory agencies responsible for oversight.
- The members and staff of the hospital's Institutional Review Board and Privacy Board
- Principal Investigator and Co-Principal Investigator(s): Amita Dave, PhD; Hilda Stambuk, MD; Nancy Lee, MD
- Members of the Research Team including the participating investigators, research assistants, clinical nurses, fellows/residents, and clerical support staff.
- Members and staff of the hospital's Office of Clinical Research, Computing Resource Group that manages research databases, and the research management and support staff in the clinical departments
- Members of the Hospital's Data Safety Monitoring Board/Committee and Quality Assurance Committee

What information will be used or disclosed?

The boxes checked below should provide you with enough detail so that you can understand what information may be used or disclosed.

- ☑ Your entire research record
- ☑ Any part of your medical records held by the hospital
- ☑ HIV-related information. This includes any information indicating that you have had an HIV-related test, or have HIV infection, HIV-related illness or AIDS, or any information which could indicate that you have been potentially exposed to HIV. (New York State requires us to obtain special consent)
- ☑ The following information: DCE-MRI, DW-MRI and MRS data

SPECIFIC UNDERSTANDINGS

By signing this form, you give permission for the sharing of your protected health information noted above. The purpose for the use and disclosure of your information, is to conduct the research study explained to you during the informed consent process. This form also ensures that the information relating to the research is available to everyone who may need it. Your protected health information may also be used for your research treatment, to collect payment for your treatment while on the study (when applicable), and to run the business operations of the hospital.

Once we have shared your information with the individuals and organizations listed on this form, they may be able to share your information again, if they are not subject to laws that protect your privacy.

It is your right to refuse to sign this authorization form. If you do not sign this form, you will not be able to participate in the research study. You will not receive the research treatment that was described to you. Your health care outside the study will not be affected. The payment for your health care or your health care benefits will not be affected.

If you sign this authorization form, you will have the right to withdraw it at any time. To withdraw the authorization will prohibit further use or disclosure of your health information. If the hospital has already use your health information approved by your authorization or needs the information to fulfill an obligation or analyze the data, the use or disclosure can not be stopped. This authorization form will not expire unless you withdraw it. If you want to withdraw this authorization, please write to Amita Dave, PhD, Department of Medical Physics at the hospital.

You have a right to see and copy your health information described in this authorization form in accordance with the hospital's policies. You also have a right to receive a copy of this form after you have signed it.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the individuals/organizations are prohibited from sharing any HIV-related information without your approval unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (800) 523-2437 or (212) 480-2493 or the New York City Commission of Human Rights at (212) 306-7450 or (212) 306-7500. These agencies are responsible for protecting your rights.

PATIENT INFORMED CONSENT FOR CLINICAL RESEARCH

Dynamic Contrast Enhanced MRI (DCE-MRI), Diffusion Weighted MRI (DW-MRI) and Magnetic Resonance Spectroscopy (MRS) of Head and Neck Tumors

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. The consent discussion will be documented in the participant's EMR.

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: _____
(If witness is used for consent discussion, their name must be documented in the EMR.)

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