THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

Phase III Randomized Trial of Intensity-Modulated Proton Beam Therapy (IMPT) versus Intensity-Modulated Photon Therapy (IMRT) for the treatment of Oropharyngeal Cancer of the Head and Neck
2012-0825

Subtitle: 2012-0825

Study Chair: Steven J. Frank

_____ _____
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 clinical research study is to compare the side effects of 2 radiation treatments for head and neck cancer. The 2 treatments are intensity modulated photon therapy (IMRT) and intensity modulated proton therapy (IMPT). Participants will also receive chemotherapy along with radiation therapy.

IMPT is designed to use beams of proton particles to send radiation to the tumor. IMRT is designed to use beams of photon therapy to send radiation to the tumor. Both of these types of radiation treatment may give a full dose of radiation treatment to the tumor while not damaging as much of the healthy tissue around it.

This is an investigational study. IMRT and IMPT are delivered using FDA-approved and commercially available methods. Comparing them is investigational.

Receiving radiation therapy may help to reduce side effects and control the disease. 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 other standard options, side effects, potential expenses, and time commitment.

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

You may continue receiving radiation therapy for up to 6 ½ weeks.

You and/or your insurance provider will be responsible for the costs of IMRT or IMPT, and chemotherapy.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive standard radiation therapy with or without chemotherapy. You may choose to receive other investigational therapy, if available. The study doctor will discuss the possible risks and benefits of these treatments. You may choose not to have treatment for cancer at all. In all cases, you will receive appropriate medical care, including treatment for pain and other symptoms of cancer.

1. STUDY DETAILS

Screening Tests

You will have screening tests to help the doctor decide if you are eligible to take part in this study. The following tests and procedures will be performed:

- Your complete medical history will be recorded.
- You will have a physical exam, including measurement of your vital signs (blood pressure, heart rate, temperature, and breathing rate) and weight.
- You will have a computed tomography (CT) scan and positron emission tomography / CT (PET/CT) scan of your head and neck to check the status of the disease.
- You will be asked how well you are able to perform the normal activities of daily living (performance status).
- Blood (about 3 teaspoons) will be drawn for routine tests.
- Leftover tumor tissue will be used for tumor marker testing. Tumor markers may be related to the status of the disease. If you do not have enough leftover tumor tissue available, you will have a tumor biopsy for tumor marker testing. The type of biopsy procedure will depend on the location of the tumor. The doctor will discuss this with you.
- If you can become pregnant, you will have a urine pregnancy test. To take part in this study, you must not be pregnant.

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

Up to 518 participants are expected to be enrolled in the entire study at all locations.

Baseline Visit

If you are found to be eligible to take part in this study, you will have a baseline visit. The following tests and procedures will be performed:

- You will be asked about your diet and if you have had recent weight loss.
- You will have a dental exam.
- Your swallowing function will be tested with a special type of x-ray called a modified barium swallow (MBS). During the test, you will eat and drink foods and liquids mixed with a "contrast" chemical called barium that will make your throat more visible in the x-rays. A special x-ray tube will be connected to a television screen to allow the doctor to watch the foods and liquids pass from your mouth and down your throat. As part of this exam, each time you will fill out a questionnaire about swallowing that should take about 5 minutes to complete.
- You will have a video-strobe procedure or laryngoscopy to allow the doctor to look at your vocal cords. To perform a video-strobe procedure, a small camera will be inserted into the throat through your nose or mouth. You will be awake for this procedure and the study staff will give you the option of receiving a numbing spray for your nose and/or throat. A laryngoscopy is a standard procedure in which a tube with a lighted camera is inserted through your mouth and into your throat.
- Photos of the inside of your mouth will be taken to check for mouth sores.
- You will fill out questionnaires about your quality of life, work status, medical history, smoking status, and any symptoms you may have. Completing these questionnaires should take about 10-15 minutes. An email address will be collected for the transmitting questionnaires. An email address will be collected for the transmitting questionnaires.
- Saliva will be collected and your jaw will be measured at this visit, at the end of your treatment, and also during follow up for 2 years. You should be fasting for a minimum of 60 minutes and instructions regarding the collection will be given.

Study Groups

You will go through the standard radiation treatment planning procedure, called the marking session. After the marking session, a standard IMRT plan and an IMPT plan will be made. If the radiation doctor thinks that both the plans are acceptable, you will be randomly assigned (as a flip of a coin) to 1 of 2 study groups:

If you are in Group 1, you will receive IMRT.

If you are in Group 2, you will receive IMPT.

If you are assigned to Group 1 but do not receive the IMRT treatment, you will be moved to Group 4. You will then have follow-up only to be asked about the status of the disease and how you are doing, as explained below.

If you are assigned to Group 2 but do not receive the IMPT treatment, you will be moved to Group 3. You will then have follow-up only to be asked about the status of the disease and how you are doing.

Study Therapy Administration

You will receive radiation therapy 1 time each day, 5 days a week (Monday through Friday) for up to 33 treatments (about 6 ½ weeks).

You will receive chemotherapy while you are receiving radiation therapy. You will be asked to sign a separate treatment consent form for these drugs with a full description of how they are given and the risks they may cause. The drugs, schedule, and doses will be your doctor's decision.

Study Visits

Every week while you are receiving radiation therapy:

- Any updates to your medical history will be recorded.
- You will have a physical exam, including measurement of your vital signs and weight.
- Blood (about 1-2 tablespoons) will be drawn for routine tests.
- You will fill out the same questionnaires as before.
- At Week 3, photos of the inside of your mouth will be taken to check for mouth sores.

You will no longer be able to receive the study therapy if the disease gets worse, if intolerable side effects occur, or if you are unable to follow study directions.

Your participation on the study will be over after you complete all the follow-up visits/contacts.

You can decide to stop taking part in this study and the study doctor will tell you how to stop safely. It is important to tell the study doctor if you are thinking about stopping so any side effects from the treatment can be looked at by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

End-of-Treatment Visit

After you finish radiation therapy (at Week 7):

- You will fill out the same questionnaires as before.
- You will have a dental exam, including jaw measurements and collection of saliva.
- Photos of the inside of your mouth will be taken to check for mouth sores.

Follow-Up (Groups 1 and 2 only)

At 8-12 weeks after finishing radiation therapy:

- You will have a dental exam, including jaw measurements and collection of saliva.
- Photos of the inside of your mouth will be taken to check for mouth sores.
- If the doctor thinks it is needed, you will have a CT scan or PET/CT scan to check the status of the disease.

During Follow-Up Months 6, 12, and 24:

- You will have an MBS exam to test your swallowing function.
- You will fill out the same questionnaires as before.
- Saliva and jaw measurements will be collected.
- Photos of the inside of your mouth will be taken to check for mouth sores.
- You will have a laryngoscopy or video-strobe procedure to allow the doctor to look at your vocal cords.

- You will have a CT or PET scan.

During Follow-Up Months 9, 16, and 20:

- Saliva and jaw measurements will be collected.
- You will fill out the same questionnaires as before.
- You will have a CT or PET scan.

Every 6 months during Follow-Up Month 30 through Follow-Up Year 10:

- At certain visits, you will have an MBS exam to test your swallowing function (2 times a year for Years 3-4 and then every 2 years or so after that).
- Saliva and jaw measurements will be collected.
- You will fill out the same questionnaires as before.
- You will have a CT or PET scan.

After you finish radiation therapy and during the 8-12 weeks while you are recovering from treatment, you will be provided with a questionnaire, by email or in paper form, that asks about any side effects you may have had. You will fill out this form every 2 weeks during this time period. Filling out the form should take about 10-15 minutes.

Filling out these forms does not take the place of your regularly scheduled follow-up visits. If you have side effects, you should also tell the study staff.

If the doctor thinks it is needed during follow-up, you will have a tumor biopsy for tumor marker testing.

Long-term Follow-up (All Groups)

The study team will contact you by phone to check your health and cancer status every 6 months for 10 years after treatment (or study enrollment, if you do not receive treatment), and then 1 time each year after that until 10 years after the last study participant was enrolled and put in a treatment group. Each phone call should take about 15-20 minutes to complete.

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 treatment is stopped, 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 study treatment.

Side Effects of Radiation Therapy to the Head and Neck

Likely (occurring in more than 20% of patients)

• fatigue • skin redness and/or irritation at the treatment site (possible dryness, itching, peeling, and/or blistering) • hair loss at the treatment site	• difficulty swallowing and eating (possible inhaling food and/or liquids into the lungs, which could also result in pneumonia) • mouth and/or throat sores	• dry mouth • changes in taste and/or smell that may be permanent • nausea • vomiting • weight loss • thick saliva

Common (occurring in 3-20% of patients)

• underactive thyroid gland (possible weight gain, heart failure, and/or constipation)	• skin damage • neck swelling • jawbone damage • hearing loss	• ear pain and/or pressure • ear infection • hoarseness

Rare but serious (occurring in fewer than 3% of patients)

• spinal cord damage • voice box damage	• tooth loss and/or cavities • sensitive teeth	• decreased movement or feeling in the arm and hand

Radiation therapy may cause an increased risk of infection, such as pneumonia. This infection may occur anywhere. It may become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing.

Radiation therapy may cause you to develop another type of cancer. Side effects may not occur for up to 6 months after radiation therapy is over.

Other Risks

Combining chemotherapy with radiation therapy may cause side effects that are not seen when each is given alone. The combination may also increase the frequency and/or severity of the side effects listed above.

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.

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about

completing the questionnaire, you are encouraged to contact your doctor or the study chair.

CT scans send x-rays through the body at many different angles. You will be exposed to a small dose of radiation. All radiation adds up over a lifetime and may increase the risk of new cancer forming. Some people may feel “closed in” while lying in the scanner. However, the scanner is open at both ends, and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or radiology technicians will give comfort, or the scanning will be stopped. Solution may also be given by vein to make the x-ray pictures more accurate. This may cause an uncomfortable feeling of warmth, nausea, and/or severe allergic reactions. The solution injection may also cause pain, bleeding, bruising, hives, and/or itching.

A **PET scan** may cause you to feel “closed in” while lying in the scanner. However, the scanner is open at both ends and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or technicians will give comfort or the scanning will be stopped.

The PET scan exposes your body to radiation. The radioactive solution does not remain in your system for a long period of time. However, you should wait 2 hours before holding an infant or getting close to a pregnant woman to avoid exposing them to radiation. You should drink fluids after the scan to help remove the solution from your system.

Your swallowing function will be tested with a special type of x-ray called **a modified barium swallow** (MBS). During the test, you will eat and drink foods and liquids mixed with a "contrast" chemical called barium that will make your throat more visible in the x-rays. A special x-ray tube will be connected to a computer screen to allow the doctor to watch the foods and liquids pass from your mouth and down your throat. Drinking the contrast agent for the modified barium swallow may cause constipation. You can avoid constipation by drinking plenty of water (or putting water through your feeding tube if you cannot drink by mouth) after the procedure. The **X-rays** taken during the modified barium swallow send a small amount of radiation though the body. All radiation adds up over a lifetime and may increase the risk of a new cancer forming.

This research is covered by a **Certificate of Confidentiality** (CoC) from the National Institutes of Health. The researchers with this CoC may not disclose or use information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information protected by this CoC cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below).

The CoC cannot be used to refuse a request of information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation. You should understand that a CoC does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any

other person not connected with the research, you must provide consent to allow the researchers to release it.

The CoC will not be used to prevent disclosure for any purpose you have consented to.

This study may involve unpredictable risks to the participants.

Pregnancy Related Risks
Taking part in this study can result in risks to an unborn or breastfeeding baby, so you should not become pregnant, breastfeed a baby, or father a child while on this study. You must use birth control during the study if you are sexually active.

Males: Tell the doctor right away if your partner becomes pregnant or suspects pregnancy.

Females: If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant, you must tell your doctor right away.

Getting pregnant may result in your removal from this study.

OPTIONAL PROCEDURES FOR THE STUDY

Optional Procedure #1: If you agree, and if tumor tissue is available, leftover tissue from earlier procedures will be stored in a research bank at MD Anderson for use in future research related to cancer. Before your samples can be used for research, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson. The IRB is a committee of doctors, researchers, and community members. The IRB is responsible for protecting study participants and making sure all research is safe and ethical.

Your samples will be given a code number. No identifying information will be directly linked to your samples. Only the researcher in charge of the bank will have access to the code numbers and be able to link the samples to you. This is to allow medical data related to the samples to be updated as needed.

Optional Procedure #2: If you agree, and if you are randomized to IMPT and/or will be treated at the MD Anderson Main Campus, blood (about 3-4 tablespoons) will be drawn for biomarker testing at time of enrollment; at Weeks 2, 4, and 6 during treatment; and at every follow up visit for up to 10 years and at time of progression. Biomarkers are found in the blood and tissue and may be related to your reaction to the study therapy.

Optional Procedure #3: If you agree, the study doctor or someone approved by the study doctor may contact you in the future to ask you to take part in more research.

Optional Procedure #4: If you agree to participate in optional functional outcomes assessments, and if you are randomized to IMPT and/or will be treated at the MD Anderson Main Campus, you will have three additional brief tests performed before you start your cancer treatment and at 6, 12, and 24 months after you finish radiation

treatments. During these tests, you will be asked to press your tongue against a bulb on the roof of your mouth, open your mouth as wide as you can, and breathe out and cough as hard as you can. Tests should take less than 10 minutes of your time with no cost incurred.

You do not have to agree to the optional procedures in order to take part in this study. There are no benefits to taking part in the optional procedures. You may stop taking part at any time. There will be no cost to you for taking part in the optional procedures.

Optional Procedure Risks:
MD Anderson and others can learn about cancer and other diseases from your **banked samples**. In the future, people who may do research with these samples may need to know more information about your health. This information may be collected from your medical record. MD Anderson will make reasonable efforts to preserve your privacy, but cannot guarantee complete privacy. Sometimes your samples may be used for genetic research about diseases that are passed on in families. Genetic research may result in the development of beneficial treatments, devices, new drugs, or patentable procedures. If this happens, there are no plans to compensate you. MD Anderson will not be able to give you, your family, or your doctor the reports about the research done with these samples, and these reports will not be put in your medical record. If this information were released, it could be misused. Such misuse could be distressing, and it could cause you or your family members to have difficulty getting insurance coverage and/or a job.

If you withdraw your consent to the storage of leftover samples in the tissue bank, then they will no longer be collected for storage. Any of your samples that remain in the tissue bank will no longer be used for research and will be destroyed.

However, if any of your de-identified samples was already released for research purposes before you withdrew consent, MD Anderson will not be able to destroy it.

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.

If you are contacted about future studies, other people may learn that you have (had) cancer. This may be upsetting.

During the functional outcomes assessments, there is a small possibility that you may feel tired or need to catch your breath after some of the breathing activities. If necessary, you will be allowed to take breaks in between the different tasks.

Optional Procedure Benefits:
There are no benefits to you for taking part in the optional procedures. Future patients may benefit from what is learned.

Optional Procedure Alternatives:
You may receive the treatment without taking part in the optional procedures. You may withdraw from the optional procedures at any time.

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

Circle your choice of "yes" or "no" for each of the following optional procedures:

Optional Procedure #1: Do you agree to have leftover tumor tissue stored in a research bank at MD Anderson for use in future research related to cancer?

YES **NO**

Optional Procedure #2: Do you agree to have blood drawn for biomarker testing?

YES **NO**

Optional Procedure #3: Will you allow the study doctor or someone approved by the study doctor to contact you in the future to ask you to take part in more research?

YES **NO**

Optional Procedure #4: Do you agree to have functional outcomes measured?

YES **NO**

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 or Massachusetts General Hospital 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. Steven J. Frank, at 713-563-2300) 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 decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. 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 without your consent at any time by the study chair, National Institutes of Health, Hitachi Chemical Co, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

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

9. This study is sponsored and/or supported by: National Institutes of Health and Hitachi Chemical Co.

Future Research

Data

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

You do not have to allow your data to be used in future research to take part in the main study. If you do not want your data to be used for future research, tell the research study doctor. However, the data already collected will be kept and may be used.

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. National Institutes of Health and Hitachi Chemical Co. will not receive leftover samples.

If you do not want your samples 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.

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.

Genetic Research
Research samples collected from you as part of this study may be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment. If genetic research is done with your samples, those who have access to those samples may be able to identify you. The results of this research may also be able to be linked to you. The same level of data protection that covers your individual data does not apply to summary results (when data from the whole study is combined).

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when deciding to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Nor does this federal law prohibit discrimination based on an already known genetic disease or disorder.

Outside Care

Part of your care may be provided outside of MD Anderson by your home doctor(s).

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

A. During the course of this study, MD Anderson will be collecting and using your 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
   - National Institutes of Health and Hitachi Chemical Co., who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

   The results of this study may be published in a medical journal or shown at medical meetings. You will not be identified (by name or any other means, for example, by photo) in any of these publications.

   Images, such as x-rays or digital pictures, taken before and/or during radiation treatments will be sent to IROC-St. Louis. Your name and other identifying information will be removed.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment 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 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. If you withdraw from the study, the study staff may ask if they can continue collecting the results of routine care from your medical record.

E. 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.

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.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under this protocol.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

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.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT