ID: UMCC 2013.062

Randomized Phase II Study of DCE-MRI-based Dose Escalation for Poor-prognosis and Neck Cancer

NCT02031250

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title: Randomized Phase II Study of DCE-MRI-Based Dose Escalation for Poor-Prognosis Head and Neck Cancer

1.2 Company or agency sponsoring the study: Radiation Oncology

1.3 Names, degrees, and affiliations of the researchers conducting the study:

Michelle Mierzwa, MD, Department of Radiation Oncology, University of Michigan

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

The purpose of this study is to compare the effects, good and/or bad, of two treatments for head and neck cancer: radiation therapy and cisplatin+radiation boost or radiation therapy and cisplatin alone. In previous studies, the investigators found that certain areas of tumors are resistant to standard doses of radiation. In order to combat these resistant areas, the researchers developed a technique called a radiation boost that delivers an increased dose of radiation to these resistant areas while standard doses will be delivered to the rest of the tumor. As a participant in this study, you will be randomized (like a flip of a coin) to one arm of the study or the other. Patients in Arm A (radiation therapy and cisplatin+radiation boost) will receive the “boost” treatment plan. Patients in Arm B (radiation therapy and cisplatin alone) will receive standard treatment. The two treatments may be comparable in treating your cancer, but radiation and cisplatin+radiation boost may result in more effective control of your tumor.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

Patients with advanced squamous cell carcinoma of the head and neck are able to participate in this study.

3.2 How many people (subjects) are expected to take part in this study?

About 120 patients will take part in this study. 80 patients will take part at the University of Michigan and 40 patients at the Ann Arbor Veterans Administration Hospital.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Eligible patients will be enrolled and will begin receiving the pre-treatment items listed below:

Pre-Treatment for Both Arms

- MRI
- Physical Exam
- Blood Tests
- Chest X-Ray
- PET-CT Scan
- Dental and/or hearing exam
- Videofluoroscopy
- Quality of Life surveys

In order to evaluate swallowing problems from radiotherapy, you will undergo an evaluation of swallowing by videofluoroscopy (VF). VF consists of swallowing a small quantity of barium, or a barium-coated food such as a cookie, while a series of x-rays are taken of the throat.

Treatment

All participants will begin receiving standard treatment of chemo-radiotherapy. You will receive radiation therapy once a day for 5 days a week, for 7 weeks. Each week you will receive a physical exam and blood tests. You will receive a cisplatin infusion once a week, beginning the same week as your radiation therapy and ending when your therapy is complete. If you are unable to tolerate cisplatin, you may be given carboplatin. It will be delivered by a pump through an intravenous catheter that goes into a vein in your arm. Before the pump delivers any drug, it will deliver several standard medications to decrease the unpleasant side effects. This is considered standard of care treatment.

During week 2 of treatment, you will receive an MRI and a PET-CT. Following this MRI, eligible participants will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. A computer program will place you in one of the study groups. Neither you nor your study doctor can choose the group you will be in. You will have an equal chance of being placed in either group.

If you are not eligible for randomization, you will continue to receive standard chemo-radiotherapy treatment as part of an observational group. During your last week of treatment, you may receive an additional MRI.

If you are randomized to Arm A, you will continue to receive standard treatment of chemo-radiotherapy as described above. At the beginning of week 4, you will begin receiving an increased dose of radiation therapy (the boost). This boost will be given at each treatment beginning at week 4 and ending at the completion of week 7. During the last week of treatment, you may receive an additional MRI.

If you are in Arm B, you will continue to receive standard treatment of chemo-radiotherapy as described above. During the last week of treatment, you may receive an additional MRI.

The following tests will be done for research purposes only:

- Additional blood tests will be done prior to therapy, at 2 weeks of therapy, 4 weeks of therapy and at 3, 6, and 12 months post therapy. The tests will be done to assess how your tumor is responding to the study treatment. During each blood test, approximately 6 ml of blood will be drawn.

Follow-up for Both Arms

You will be asked to return to the clinic for check-ups at 1 month after the completion of therapy and then every 2 months during years 1 and 2, and at 3-month intervals during year 3. At each of these visits you may undergo a physical exam, blood tests, quality of life surveys, and/or videofluoroscopy. At 10-14 weeks following treatment, and again at 11-13 months following treatment, you will have a PET-CT scan.

4.2 How much of my time will be needed to take part in this study?

Typically, a course of radiation lasts 6-7 weeks and treatments are delivered each day, Monday through Friday, each week. Each radiation treatment lasts approximately 10-20 minutes. Cisplatin or carboplatin infusion will require a couple hours once weekly during this time period.

Follow-up visits last about 1 hour each.

4.3 When will my participation in the study be over?

After your radiation treatment is completed, you will return for follow-up appointments one month after treatment, then every 2 months during years 1 and 2, and at 3-month intervals during year 3. Your follow-up visits related to the research will end after 3 years.

4.4 What will happen with my information and/or biospecimens used in this study?

Your collected information and biospecimens may be shared with the University of Michigan Radiation Oncology team. Your collected information and biospecimens may also be shared with other researchers, both here or around the world, or with companies. Any sharing is subject to contractual obligations with the Sponsor. Additionally:

• With appropriate permissions, your identifiable collected information [and biospecimens] may be shared, and/or,

• Without your additional consent, your identifiable private information [and identifiable biospecimens] may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies.

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

Risks and Side Effects Related to Radiation Therapy of the Head and Neck

Very Likely

- Sores in the mouth and/or throat which can be painful and make it very difficult to chew and or swallow foods
- Mouth dryness or changes in taste and/or smell that may be permanent
- Thick saliva
- Hoarseness
- Tanning or redness and/or irritation of the skin in the head and neck area being treated with radiation
- Ear pain and/or pressure
- Fatigue
- Weight loss
- Permanent hair loss in the area treated with radiation (face, chin, neck)
- Loss of teeth, or cavities in the teeth, if strict dental care is not followed and/or hypersensitivity of teeth

Less Likely, But Serious

- Decrease in function of the thyroid gland that may require you to take thyroid replacement medicine to prevent you from feeling tired or sleepy
- Serious damage to the spinal cord, nerves in the neck, jawbone, voice box, skin, or other parts of the head and neck that may require a major operation to correct and, rarely, can even be life threatening
- Temporary pain or scarring around nerves in the shoulder that could cause numbness and/or weakness
- Breathing problems
- Difficulty with swallowing and eating for which you might need a long term or permanent feeding tube; possibility of inhaling food and/or liquids into the lungs – which could also result in pneumonia.
- Serious ear infections and/or hearing loss
- Damage to the spinal cord leading to permanent weakness and/or symptoms like a "stroke". Stroke has been reported to be slightly higher after head and neck radiation, compared with the general population, due to the possibility of increased formation of plaque in the carotid artery (causing blockage).

All these side effects may be a result of standard radiation treatment, as well as radiation according to this study. Your physicians do not know whether the chance of complications arising from participation in this study is different from the chance of complications arising from standard radiation.

Risks and Side Effects Related to cisplatin

Likely

- Decrease in blood counts that can lead to a risk of infection and bleeding
- Loss of appetite and/or taste; metallic taste in your mouth
- Nausea and/or vomiting
- Hearing loss or ringing in the ears
- Numbness or tingling in the hands and feet

Less Likely

- Muscle cramps or spasm
- Loss of coordination
- Involuntary movements or shaking
- Rash
- Vision problems
- Hair loss
- Low mineral levels in your blood
- Decrease in liver function causing temporary elevation in blood tests

Rare but Serious

- Loss of muscle or nerve function, which may cause weakness or numbness in your hands and feet
- A decrease in the kidneys' ability to handle the body's waste, which may be permanent
- Allergic reactions that can cause difficulty breathing, fast heartbeat, and sweating
- Another cancer called acute leukemia

Risks and Side Effects Related to carboplatin

The known side effects of carboplatin are: Lowered number of white cells (important in fighting infection), bruising or bleeding, anemia (low number of red blood cells important for carrying oxygen around the body),

nausea and vomiting, renal toxicity, abnormal liver function, loss of appetite, tiredness, weakness, tingling and numbness of hands and feet, changes in hearing, diarrhea, sore mouth (ulcers), taste changes, hair loss and rarely allergic reactions (signs of allergic reaction are rash, fever, breathlessness, facial swelling and need to pass urine). Carboplatin can cause harm to the fetus when administered to a pregnant woman; therefore, you are advised to use an adequate method of birth control while in the study.

PET/CT scanning using [18F]FDG and Diagnostic CT scan. PET/CT scanning is associated with several risks, as follows:

The PET/CT protocol at UM includes a dedicated diagnostic head and neck CT with intravenous contrast and there is a potential risk for allergic reactions to the intravenous iodinated contrast. A dose of 100 ml of iodinated contrast (Isovue) is given in the veins for the CT. Allergic reactions to contrast are infrequent, overall occurring in 0.2-0.7% cases, however severe or even life-threatening reactions may rarely occur. Any patient with a history of prior allergic-like reaction to iodinated contrast (of any severity), with symptoms such as hives, itching, acute rash, wheezing, bronchospasm, stridor, laryngeal edema, anaphylaxis, would be eligible for steroid preparation prior to the contrast injection, either oral or IV combination of steroids and diphenhydramine. In the event of an allergic reaction during the PET/CT, trained personnel, doctors, nurses and technologists are on hand to provide specific treatments depending on the symptoms and the type of reaction.

Intravenous line (IV) for radiotracer injections: There is an infrequent risk of bruising, bleeding, infection, or soreness associated with intravenous catheter placement, similar to the risks associated with routine blood testing. Subjects might feel dizzy or lightheaded or may rarely even faint when the tube is put in or taken out. The risk of these side effects is minimized by using highly trained personnel.

Low-level Radiation Exposure: During the course of this study, subjects will be exposed to radiation from the PET radiotracer 2-[18F]fluoro-2-deoxy-D-glucose ([18F]FDG), a radioactive form of sugar. The biological effect of radiation exposures is measured in milli-Sieverts (mSv), which is a unit of whole body radiation exposure, called the 'effective dose'. The total amount of radiation you will be exposed to in this portion of the research study will result in a total effective dose less than 13 mSv. The PET/CT scan using [18F]FDG has a total effective dose of 10.4 mSv, and the diagnostic head-and-neck CT study has an effective dose of 2.5 mSv. Together, the PET/CT and diagnostic CT study have a total effective dose = 10.4 + 2.5 = 12.9 mSv.

The effects on your body of this radiation exposure will be added to your overall life-time radiation risk. Your life-time radiation risk includes the background radiation you are exposed to naturally like everyone else living on this planet, which is on the average 3 mSv per year. The radiation you will be exposed to in this study is about 4.3 times the yearly background radiation. In terms of radiation a person may get exposed to during medical care, the amount you will receive in this study will be less than 1.6 times the amount of radiation received in a CT scan of the chest, which is about 8 mSv. The Federal Government requires that the amount of radiation exposure of radiation workers does not exceed 50 mSv per year; the radiation you will be exposed to in this study is about one-fourth that amount. Your life-time radiation risk also includes any radiation you may have received in the past for diagnosis or treatment, and any such radiation you may be exposed to in the future. The risk from radiation exposure of this amount is considered to be similar to other every day risks, such as driving a car. No PET studies will be performed on pregnant, nursing, or potentially pregnant women, as determined by pregnancy testing within 48 hours prior to PET the scanning session.

The researchers will try to minimize the risks (above) by:

PET/CT and CT scanning: Skilled nuclear medicine technologists will perform the PET/CT and CT studies under the supervision of a physician who is a specialist in nuclear medicine. We will use aseptic techniques and highly trained

personnel to minimize the risks associated with venipuncture (IV). A physician or nurse will be available at all times during the study, and any adverse reactions will be treated immediately. A fully equipped medical cart is located in the PET facility. No PET studies will be performed on pregnant, nursing, or potentially pregnant women, as confirmed by pregnancy testing (b-HCG) performed within 48 hours prior to each PET scanning session for women of childbearing potential.

Risk to embryo or fetus:

If appropriate, you will be asked if there is a possibility that you may be pregnant. You may not take part in this project if you are pregnant. If you are or may become pregnant, this research may involve unforeseeable risks to you, the embryo, or the fetus.

To minimize this risk, sexually active women with child-bearing potential must be using adequate contraceptive measures. If there is a question of pregnancy, a pregnancy test will be done without any cost to you

Risks and Side Effects Related to MRI

MRI scans are hazardous for people with certain specific surgical implants. These include cardiac pacemakers, some heart valves, surgical clips used to treat abnormal blood vessels, metal filters used to treat blood clots, and other less commonly used devices. *You must inform the MRI staff of all surgeries you have had to make sure that you do not have any of these implants.*

Although the MRI is well lit, open at both ends, ventilated, and has an intercom, some people experience claustrophobia (fear of enclosed spaces). There is a risk that you might experience discomfort or anxiety from being in the MRI scanner. You will be provided with pads and blankets to make you as comfortable as possible. You will be given foam earplugs to reduce the load noises made by the scanner. You will be able to talk throughout the procedure and let the medical staff know right away if you want to stop the procedure and get out of the scanner. A physician will be immediately available in the MRI area and experienced radiology technologists will conduct the procedures.

The placement of an IV for the injection of the MRI contrast material may be associated with minor discomfort and bruising at the site. This usually requires no treatment. It is possible that an infection can occur at the site of the IV. This is very rare, but if an infection occurs, it would require medical attention. The contrast agent, gadolinium, may cause headache, nausea, and local burning. Although it is very unlikely, subjects could experience an allergic reaction to the contrast agent. Such a reaction could be mild or severe and would require medical treatment.

Reproductive Risks

If appropriate, you will be asked if there is a possibility that you may be pregnant. You may not take part in this project if you are pregnant. If you are or may become pregnant, this research may involve unforeseeable risks to you, the embryo or the fetus.

WOMEN

There could be risks to a fetus in this study. If you are pregnant or become pregnant during the study, these risks could affect you or your fetus. Women must agree to either abstain from sexual activities that could result in pregnancy or use at least one acceptable method of birth control (i.e. condom, IUD, pill) while taking part in this study.

You should not nurse (breast feed) while receiving cisplatin and radiation therapy as these treatments negatively affect breast milk and may harm your child.

MEN
Men must agree to either abstain from sexual activities that could result in pregnancy or use an acceptable form of birth control while taking part in the study Acceptable forms of birth control are male latex condom (with or without spermicide) or vasectomy. You should not donate sperm for one month after the last dose of study treatment.

The radiation treatment and the drug may cause harm to your unborn baby. You must take adequate contraceptive measures while taking part in this study, whether you are a man or woman. Appropriate methods of birth control include birth control pills, Depo-Provera, Norplant, intrauterine device (IUD), diaphragm + spermicide, and condom + spermicide. Please ask your physician if you would like additional information about preventing pregnancy. If you are not willing to use adequate methods of birth control, you should not take part in this study.

Risk Reduction:
Your doctor will see you on a weekly basis during treatment to assess the side effects. Physical examinations, scans and other routine tests will be done to monitor the effects of the treatment. Although many side effects disappear after radiation therapy has been completed, some are permanent. You understand that you may ask your doctor about these side effects. You will be informed about ways to minimize sore mouth and throat during radiation therapy, including rinsing the mouth with salt and soda solutions. Appropriate pain medication and other measures which will be taken by your nurses and doctors as necessary. Close follow-up will be performed after radiation is completed, to assess any long-standing side effects of radiation.

Before each treatment of cisplatin you will receive standard medications to decrease the chances that you will experience nausea, vomiting, and an allergic reaction. These medications will be determined by your medical oncologist. Your heart rate and blood pressure will be monitored during your cisplatin treatments. Because fever is a sign of infection, and you will be at an increased risk for infection during therapy, it is important that you contact your physician if you develop a fever during treatment in order that appropriate treatment can be started. Frequent blood samples will be taken to monitor the number of white blood cells, red blood cells, and platelets you have in your blood to monitor how the treatment is affecting your body. If your body can not make enough white blood cells, red blood cells, and platelets due to the treatments, your physician will begin appropriate treatment. If you develop severe redness of your skin or pain in your mouth and throat your physician may temporarily hold or modify your cisplatin or carboplatin treatment. If you are able to resume cisplatin or carboplatin, you may be given a lower dose of the medication in order to decrease the risk of redness of your skin and pain in your mouth and throat.

As with any research study, there may be additional risks that are unknown or unexpected.

Genetic Information Nondiscrimination Act (GINA) – If the research involves genetic analysis of biological samples, insert the following two paragraphs:

The federal 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 does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Under this law:

- Health insurance companies and group health plans may not request your genetic information that we obtain 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 obtain from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment

GINA does not apply to the following groups, however these groups have policies in place that provide similar protections against discrimination:

- Members of the US Military receiving care through Tricare
- Veterans receiving care through the Veteran's Administration (VA)
- The Indian Health Service
- Federal employees receiving care through the Federal Employees Health Benefits Plans

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

5.3 If I take part in this study, can I also participate in other studies?
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.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. However, there is a chance that the boost may improve tumor control and increase the length of disease-free survival.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?
If you decide not to participate, you will be treated with the best standard therapy, according to the clinical judgment of your physicians.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information" (below).

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
We do not anticipate any harm to you if you leave the study as long as you continue with standard therapy according to the judgment of your physicians.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- ✓ The researcher believes that it is not in your best interest to stay in the study.
- ✓ You become ineligible to participate.
- ✓ Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- ✓ You do not follow instructions from the researchers.
- ✓ The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researchers' number listed in section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

The study team has given you instructions about this research study. It is important that you follow these instructions carefully. If you get sick, have a medical complication, or are injured as a result of your being in the study, call Dr. Mierzwaimmediately, at 734-936-4300. The doctor will either treat you or send you to another doctor for treatment. You will get free hospitalization for any complication, injury, or illness caused by the study drug, device, or procedure. The UMHS and the study doctor are responsible for determining whether your condition was the result of your participation in the study. The UMHS will pay for hospitalization only if it has been caused by the study drug, device or procedure. This means that you or your health plan must pay for any treatment that is part of your usual medical care or that is related to a medical condition you had before participating in the study.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
You will not be paid for taking part in this research.

8.3 Who could profit or financially benefit from the study results?
Neither the researchers nor the University of Michigan will financially benefit from the results of this study. Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy?

We shall put the information collected about you during the study into a research record. This research record will be linkable to you. However, we shall keep your research record confidential, to the extent provided by federal, state and local law. We shall not allow anyone to see your record, other than people who have a right to see it. You will not be identified in any reports on this study.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Mental health care records (except psychotherapy notes not kept with your medical records)
- Alcohol/substance abuse treatment records
- Your AIDS/HIV status
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Billing information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA), and/or other government officials may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

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.

9.3 What happens to information about me after the study is over or if I cancel my permission?
As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web athttp://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission expire?
Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below).

10. CONTACT INFORMATION

10.1 Who can I contact about this study?
Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Michelle Mierzwa, MD
Mailing Address: Radiation Oncology
1500 E. Medical Center Dr.
UH B2 C440
Ann Arbor, MI 48109-5010
Telephone: 734-936-4300

You may also express a concern about a study by contacting the Institutional Review Board listed below.

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies: US Country Code: 001)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

This "Consent to be Part of a Research Study" document. *(Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

_____

Date of Birth (mm/dd/yy): _____

ID Number: _____

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

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PERSONAL CENSUS FORM

Name _____ Date _____

The National Cancer Institute requires that The University of Michigan Comprehensive Cancer Center report race and ethnicity information about people who participate in clinical research to ensure that all populations are offered the opportunity to participate.

☐ Check here if you do not wish to provide some or all of the information below.

1. What race do you consider yourself to be? (Please select *one or more*)
   - ☐ American Indian/Alaska Native[a]
   - ☐ Asian[b]
   - ☐ Black or African American[c]
   - ☐ Native Hawaiian or Other Pacific Islander[d]
   - ☐ White[e]
   - ☐ More than one race[f]

2. Do you consider yourself to be Hispanic[g]? ☐ Yes ☐ No

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[a] American Indian or Alaska Native- A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliation or community attachment.

[b] Asian- A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand and Vietnam.

[c] Black or African American- A person having origins in any of the black racial groups of Africa. (Terms such as “Haitian” or “Negro” are sometimes used in addition to “Black” or “African American.”)

[d] Native Hawaiian or Other Pacific Islander- A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

[e] White- A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

[f] More than one race- (It is preferred that this be selected in addition to the selection of the specific races listed above, but this may also be solely selected.)

[g] Hispanic or Latino- A person of Mexican, Puerto Rican, Cuban, Central or South American, or other Spanish culture or origin, regardless of race. The term “Spanish origin” is sometimes used in addition to “Hispanic” or “Latino.”