Informed Consent Form

NCT05120947

Official Title: A Phase I Study of Hypofractionated Adjuvant Radiotherapy for Resected Head and Neck Cancers (HART-HN)

October 23, 2024

EFFECTIVE

10/23/2024

MCW IRB

Medical College of Wisconsin
INTRODUCTION TO THE INFORMED CONSENT

IIT-AWAN-HART-HN: A Phase I Study of Hypofractionated Adjuvant Radiotherapy for Resected Head and Neck Cancers (HART-HN)

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Definitions

Hypofractionated Radiotherapy – a method of radiation therapy that gives the same total dose of radiation to tumor cells over a smaller number of fractions (shorter period of time) at higher doses of radiation per fraction, as compared to standard radiation therapy.

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Purpose

This project is being done to determine whether hypofractionated radiation therapy or the reduction of radiation treatment fractions (to 10, 8, or 5 instead of 30) may be delivered in resected Head and Neck Squamous Cell Carcinoma (HNSCC) patients with intermediate pathologic risk features.

Length

1. You will be in this research project for about 13 months, including Screening time and Follow-up visits.
   - We would also like to follow you every other week for the first 6 weeks, and at 3, 6, 9, and 12 months from the end of your radiation treatments.

Procedures

All study participants will have hypofractionated adjuvant radiation therapy for resected head and neck cancers.

List of visits:

- Screening Visit(s)
  - Total Number: approx. 2-4
  - Total Time: approx. 4-8 hours
- Pre-intervention Visit(s)
  - Total Number: approx. 2
  - Total Time: approx. 2-4 hours
- Treatment Visit(s)
  - Total Number: approx. 5-10
  - Total Time: approx. 4-8 hours
- Follow-up Visit(s)
  - Total Number: approx. 7
  - Total Time: approx. 3 hours each

Procedures that will occur at various visits:

Invasive Procedures

- Blood collection for laboratory tests, including pregnancy testing, when applicable
- CT or MRI scans, when contrast is utilized

Non-invasive Procedures

- History and physical exams visits
- CT/MR simulation
- Radiotherapy
- Speech language evaluation
- Videofluoroscopic swallow study
- Study questionnaires

Risks

This is a brief list of the most commonly seen side effects. The ***full consent form*** after this introduction contains a more complete list of potential research risks.

Radiation Therapy risks:

- Sores in mouth and throat which may be painful especially with swallowing
- Dry mouth
- Loss of taste buds
- Thick saliva
- A skin burn that looks like a sunburn
- Fatigue
- Pain requiring numbing or pain medicine
- Unable to eat requiring a feeding tube
- IV fluids for dehydration
- Scar tissue in neck
- Difficulty opening your mouth
- Swallowing difficulty with big bites and dry food

Benefits

We don't know if this project will help you. Your condition may get better but it could stay the same or even get worse.

My Other Options

You do not have to join this project. Your other options may include:

1. Joining a different project
2. Routine care for this condition
3. Getting no treatment for this condition

If you have more questions about this project at any time, you can call Musaddiq Awan at 414-805-6700.

If you have questions about your rights as a participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

CONSENT TO PARTICIPATE IN RESEARCH

A1. INTRODUCTION – WHY ARE WE ASKING YOU TO PARTICIPATE?

You are being invited to participate in this research because your resected head and neck cancer was found to have intermediate pathologic features, warranting adjuvant radiation therapy.

A total of about 18 people are expected to participate in this research including about 15 at the Medical College of Wisconsin/Froedtert Hospital. Remaining subjects will participate at the Clement J. Zablocki Veterans Affairs Medical Center.

The Director of the project is Musaddiq Awan, MD in the Departments of Radiation Oncology. A research team works with Dr. Awan. You can ask who these people are.

This project will be funded by the MCW Radiation Oncology ROCKET research program.

A2. DO I HAVE TO PARTICIPATE?

You can decide whether to take part in this research or not. You are free to say yes or no. If you do not agree to join, or if you leave, you will not be penalized or lose any benefits that you had before starting the research project. Even if you join this project, you do not have to stay in it. You may stop at any time. Take as much time as you need to make your choice.

A research project is different from routine medical care in three ways: 1) there are extra risks that we will tell you about in this form; 2) you may have some extra medical tests and visits; 3) the research procedures, tests and visits follow a set plan that must be kept.

A3. WHY IS THIS PROJECT BEING DONE?

The standard approach to treat resected head and neck tumors with intermediate pathologic features is conventional post-operative radiation therapy for about six weeks in 30 low-dose fractions. In this study, we want to find out whether the reduction of the radiation treatment fractions (to 10, 8, or 5 instead of 30) may be delivered in resected Head and Neck Squamous Cell Carcinoma patients. Everyone in this study will receive hypofractionated radiation therapy to determine the minimum number of fractions that may be delivered safely.

Your condition may get better, but it could stay the same or even get worse. We hope the information from this study will help us develop a better treatment for head and neck cancers in the future.

B1. WHAT WILL HAPPEN IF I PARTICIPATE?

Study Treatment

All subjects in this study will receive hypofractionated adjuvant radiation therapy, which will be subject to fractionation reduction, that being 10 fractions, 8 fractions, or 5 fractions, as compared to 30 fractions of conventional radiation therapy.

If you participate in this study, you will receive smaller number of fractions (total visits) but with a higher dose of radiation. You will receive a total radiation dose of 42 Gy in 10 fractions (Dose Level 1), or 39 Gy in 8 fractions (Dose Level 2), or 32.5 Gy in 5 fractions (Dose Level 3), depending on the assigned experimental total fractions. Radiation will be delivered using intensity modulated radiation therapy (IMRT) with a daily cone-beam CT for 5 days a week, for less than 2 weeks depending on the assigned dose level at the time of your enrollment.

Study Visits

The study is divided into 4 periods: Screening, Pre-Intervention, Intervention, and Follow-up.

Screening
After you sign the informed consent form, you will visit the clinic to see if you are eligible to participate in the study. The study team will ask you some questions about your health and medications you are taking, perform a physical exam, and run some tests to determine if you are eligible. If some of the tests were completed recently, they may not have to be repeated for the study.

Pre-Intervention
The Pre-Intervention period will consist of standard radiotherapy simulation including CT simulation and/or MRI simulation and radiation treatment planning. This will be done with and without contrast. You will also be seen by a speech and language pathologist and undergo videofluoroscopic swallow studies and graded as per standard institutional guidelines. Further, you will be asked to complete quality of life questionnaires during this period.

Intervention
The Intervention period will consist of undergoing daily radiotherapy on a Monday-Friday basis for the total number of experimental fractions. Quality of life questionnaires will be completed on the last session of radiotherapy.

Follow-up
You will then return to the clinic bi-weekly for the first 6 weeks, and at 3, 6, 9, and 12 months from the end of your head and neck radiation therapy. During this period, surveillance imaging including a CT or MRI of the neck and Chest CT or PET/CT will be done to assess how you are responding to treatment, as per local institutional guidelines. Quality of life questionnaires will also be done at each time point.

Study Assessments

Screening

You will need to have all or some of the following exams, tests, or procedures to find out if you can be in the study. They may be done even if you do not join the study. If some of the tests were completed recently, they may not have to be repeated.

- Informed consent: Prior to any study-related procedures being performed, you will be required to voluntarily sign and date this consent form.
- Physical examinations: You will receive a complete physical examination by Radiation Oncology and Surgical Oncology, including weight and height.

- Vital signs: Your blood pressure, temperature, and heart rate will be checked.
- Performance status: An assessment of your overall health and ability to perform daily tasks
- Medical history: You will be asked about your health status, including previous treatments for your cancer
- Medications: You will be asked about any changes in your current medications, including over-the-counter medications, vitamins, and herbal supplements
- Blood or urine tests
    - A blood or urine sample will be collected for pregnancy, if you are a female patient capable of having children.
    - Blood will be collected to test organ function
- Neck CT or MRI: You will have a neck or head and neck CT or MRI for tumor surveillance.
- Chest CT or PET/CT: You will have chest CT or PET/CT for tumor surveillance.

Pre-Intervention

The following assessments or activities will be done during the pre-treatment period of the study.

- CT/MR simulation: Standard radiation therapy simulation that involve CT or MR imaging will be done with and without contrast to facilitate radiation treatment planning.
- Radiation planning: Your radiation oncologist will plan your treatment in accordance with study protocol and local institutional guidelines.
- Quality of Life questionnaires: Questions about daily activities and mental, physical and emotional symptoms, etc.
- Speech Language Pathology (SLP) evaluation: Your speech language pathologist will complete a communication evaluation prior to start of study treatment, as per institutional guidelines.
- Total opioid intake assessment: a list of the opioid medications you are currently taking, to assess the pain you are experiencing.
- Videofluoroscopic Swallow Study (VFSS): Your speech language pathologist will complete a swallow study to assess how well you swallow food and liquid, as per institutional guidelines.

Intervention

The following assessments or activities will be done during the study intervention period of the study.

- Physical examinations: You will receive a complete physical examination by Radiation Oncology and Surgical Oncology, including weight and height.
- Vital signs: Your blood pressure, temperature, and heart rate will be checked.
- Performance status: An assessment of your overall health and ability to perform daily tasks
- Medications: You will be asked about any changes in your current medications, including over-the-counter medications, vitamins, herbal supplements, and opioid medications
- Radiation therapy: You will receive 10, 8, or 5 radiation therapy fractions, depending on treatment assignment, following study registration. Radiation therapy will be given 5 days a week.
- Quality of Life questionnaires: Questions about daily activities and mental, physical and emotional symptoms, etc.

Follow-up

Following completion of adjuvant radiation therapy, you will return to clinic every 2 weeks for the first 6 weeks, and at 3, 6, 9, and 12 months. The following assessments or activities will be done during the follow-up period of the study.

- Physical examinations: You will receive complete physical examinations by Radiation Oncology and Surgical Oncology, including weight and height.
- Vital signs: Your blood pressure, temperature, and heart rate will be checked.
- Performance status: An assessment of your overall health and ability to perform daily tasks.
- Medications: You will be asked about any changes in your current medications, including over-the-counter medications, vitamins, herbal supplements, and opioid medications
- Speech Language Pathology (SLP) evaluation: Your speech language pathologist will complete a communication evaluation prior to start of study treatment, as per institutional guidelines.
- Video Fluoroscopic Swallow Study (VFSS): Your speech language pathologist will complete a swallow study to assess how well you swallow food and liquid, as per institutional guidelines.
- Quality of Life questionnaires: Questions about daily activities and mental, physical and emotional symptoms, etc.
- Neck CT or MRI: You will have a neck or head and neck CT or MRI for tumor surveillance at around 3 months post radiation.
- Chest CT or PET/CT: You will have chest CT or PET/CT for tumor surveillance at around 3 months post radiation.

B2. HOW LONG WILL I BE IN THE PROJECT?

You will be in this research project for approximately 13 months, including screening, study treatment, and follow-up visits.

After radiation therapy is completed, we will ask you to return to clinic for follow-up care as described above, to monitor your health. We will ask you to return to clinic at 2, 4, and 6 weeks, and at 3, 6, 9, and 12 months after completion of study treatment.

B3. CAN I STOP BEING IN THE PROJECT?

You are free to withdraw from the project at any time. If you leave, your regular medical care will not change. If you are thinking about leaving, please tell the research doctor.

The research doctor can tell you about the effects of stopping, and you and the research doctor can talk about what follow-up care would help you the most.

You might be asked to come back for one more visit to check your health.

The research doctor may take you out of this project at any time. This would happen if:

- They think it is in your best interest.
- You do not follow the project rules.
- The whole project is stopped.

If this happens, the research doctor will tell you.

B4. ARE THERE ANY SPECIAL INSTRUCTIONS WHILE I AM IN THE PROJECT?

You should not breastfeed a baby during the project.

You should refrain from taking any radiation sensitizing agents (e.g., methotrexate, gemcitabine, docetaxel, carboplatin, cisplatin) while receiving study treatment.

C1. WHAT HEALTH RISKS OR PROBLEMS CAN I EXPECT FROM THE PROJECT?

There are risks to taking part in any research project. There is a risk that you may get radiation treatment that does not help your condition or may make it worse. There also may be problems (side effects) we do not know about yet, from the radiation treatment offered in this study. If we learn about new important side effects, we will tell you.

We watch everyone in the project for problems (side effects). **You need to tell the research doctor or a member of the research team immediately if you experience any problems, side effects, or changes in your health.** In an emergency, call 911.

C2. RISKS OF HYPOFRACTIONATED RADIOTHERAPY

The research radiotherapy itself may cause problems (side effects). Side effects may be mild or very serious. Some can last a long time or never go away. Not all toxicities related to study treatment are known at this time.

RADIATION THERAPY RISKS

The following are side effects associated with standard head and neck radiation therapy:

Likely (20% or greater of the time):

- Sores in mouth and throat which may be painful especially with swallowing
- Dry Mouth
- Changes in taste, loss of taste bud
- Reduced sense of smell
- Thick saliva
- Hoarseness
- A skin burn that looks like a sunburn
- Fatigue
- Weight loss
- Permanent hair loss in the area of radiation
- Pain requiring numbing or pain medicine

Less Likely (occurs 10-20% of the time):

- Unable to eat requiring a feeding tube
- IV fluids for dehydration
- Scar tissue in neck
- Difficulty opening your mouth
- Swallowing difficulty with big bites and dry food
- HSV1/HSV2 reactivation (oral soreness, blisters, rash)

Rare but serious (2-10% of the time):

- Bleeding or Carotid blowout – leaky blood vessel in your neck that can bleed. A carotid blowout can be fatal.
- Infection
- Non-healing wound
- Mandible necrosis – the jaw bone gets weak or fractures
- Teeth damage/loss
- Soft tissue necrosis
- Osteoradionecrosis
- Need of tracheostomy

- Permanent feeding tube
- Death
- Radiation induced cancer

In addition to radiation therapy you may receive additional radiation from diagnostic procedures to evaluate your condition. The principal risk associated with a radiation dose is the possibility of developing a radiation-induced cancer later in life. However, the additional risk of radiation-induced cancer from these diagnostic procedures is low compared to the risks from the radiation therapy.

C3. OTHER RISKS OF THIS RESEARCH PROJECT

Other procedures that are part of the research also involve some risks:

Blood collection
Blood collection may cause some discomfort, bleeding, or bruising at the puncture site. A small blood crust or swelling may occur at this site. In rare cases, fainting or local infection may occur. If you feel discomfort during blood collection, please report this to the study doctor or staff at the time.

Magnetic Resonance Imaging (MRI Scan)
MRI, which uses a large magnet instead of x-rays to take pictures of your body, you may feel mild vibrations throughout your body. The machine will produce a loud knocking noise. This is normal. You will be given earplugs to protect your ears. Some people, especially those who tend to feel uncomfortable in small or closed spaces, may feel “closed in” and become anxious while in the scanner. The scanner has an intercom, which will allow you to speak to the staff during the procedure. If you feel ill or anxious during scanning, tell the MRI staff and the scanning will be stopped if you wish.

The MRI will require a catheter to be inserted into one of your veins in order to inject the MRI contrast agent. This may cause skin irritation, bleeding, and/or infection. You may have an allergic reaction to the contrast agent.

The magnetic field used in MRI scanning may harm people who have metal in their bodies (pacemakers, neurostimulators, certain clips, or staples from surgery). It may cause problems with devices, such as pacemakers. If you have metal in your body or a pacemaker, you should not have an MRI. Your study doctor will discuss with you whether you should have a MRI scan with a contrast agent based on your health status.

PET/CT
The risks with a PET/CT scan include:

- Exposure to radiation. The amount of radiation from one PET/CT scan will depend on the area of the body being scanned but is generally about equal to 10 years of background radiation (the amount that you would be exposed to from sunlight and other sources in your everyday life).
- Possible allergic reaction to the contrast dye used to help doctors see the different organs and your cancer better. These scans may involve dyes being injected into one of your veins. There is a risk of allergic reaction to the dye. This reaction may be mild (such

as a skin rash or hives) to severe (such as breathing difficulties and shock). There is a risk that the injection of dyes may cause:

- Pain
- Swelling
- Bruising
- Irritation, or redness at the injection site
- Feeling faint
- Infection (rare)

Your study doctor may take steps to prevent these risks from happening. He or she may recommend medications that may help with these side effects. You may be asked to sign a separate consent form for these procedures.

Quality of Life Questionnaires
The answers that you give are confidential, but there is always a risk that your answers will be read by people who should not read your personal information. You may also feel uncomfortable completing some of the assessments.

Privacy and Confidentiality
Another risk may be loss of confidentiality. Every effort will be made to keep your research records confidential but we cannot guarantee it. Depending on the kind of information being collected, if your research information were accidentally seen, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the project director about whether this could apply to you.

C4. REPRODUCTIVE RISKS

Risks to subjects who could become pregnant
We know the radiation in this project affects babies, so we do not want anyone who might be pregnant to enter the project.

You should not become pregnant or nurse a baby while in this project. You must tell the research doctor right away if you think you are pregnant. You will be asked to have a pregnancy test to be sure you are not pregnant at the start of the project.

You may not donate eggs during your participation in the project.

If you become pregnant during the project, you will be withdrawn from participation for safety reasons. If you become pregnant while you are undergoing radiotherapy treatment, we ask that you inform the research doctor immediately. The research doctor will ask you for written permission to obtain information from you or your obstetrician on your pregnancy and the health of the baby.

Risks to a subject who could father a child and the subject's partner(s)
If you and your partner(s) are able to become pregnant, one or both of you must use some form of effective birth control, because we know that the radiation affects babies. You must tell the research doctor right away if you think your partner is pregnant.

You may not donate sperm during your participation in the project.

If you think you have gotten your partner pregnant while undergoing radiation, we ask that you inform the research doctor immediately. At that time, the research doctor will ask permission of your partner for the use and disclosure of health information regarding the pregnancy. Your partner will be asked to sign a separate consent form and can choose to do this or not. Your partner will be asked to sign this form to allow your research doctor to contact your partner's obstetrician to collect information on the progress of the pregnancy and its outcome. The research doctor will make this information available to the sponsor for safety monitoring.

Birth control methods for all subjects
Check with the research doctor about the birth control methods needed for this project and how long to use them. Some methods might not be good enough for this project. If you are having sex that could lead to pregnancy, you should use one form of birth control while you are in this project.

This may include:

- Not having vaginal sex (abstinence)
- Taking birth control pills orally
- Having birth control shots or patches such as Depo-Provera
- Surgical sterilization (hysterectomy/tubal ligation or vasectomy)
- Limiting sexual activity to a partner who has undergone surgical sterilization
- Use of an intrauterine device (IUD)
- Use of diaphragm with contraceptive jelly
- Use of condoms with contraceptive foam
- Use of diaphragm with condoms ("double barrier")

You should continue using birth control for 180 days (6 months) after stopping radiation treatment.

C5. ARE THERE ANY BENEFITS TO TAKING PART IN THE PROJECT?

We don't know if this study will help you. Your condition may get better, but it could stay the same or even get worse. We hope the information from this study will help us develop better treatments for resected head and neck cancer patients.

D1. ARE THERE ANY COSTS TO BEING IN THE PROJECT?

Most of the medical care that you will receive in this project is considered routine care for your condition and would be recommended whether or not you join the project. Costs for routine care will be billed to you or your insurance carrier. For routine clinical care, you will be responsible for paying any copayment, coinsurance, or deductible that is required by your insurance carrier.

Activities / costs that are part of the project will not be billed to you or your insurance company. These are:

- Quality of Life questionnaires

Some insurers will not pay for drugs, tests or hospitalization that are part of research, so check with your insurer before you join this project. If you have questions regarding costs, please contact Dr. Awan.

If you participate in this research, the costs of any necessary emergency medical treatment in the event of a research-related injury will be billed to you or your health insurance.

D2. WILL I BE PAID FOR PARTICIPATING IN THE PROJECT?

There is no payment for being in this project.

D3. WHAT OTHER HEALTHCARE CHOICES DO I HAVE?

You do not have to join this project. You are free to say yes or no. If you do not join this project, your research doctor can discuss other healthcare choices with you.

Your other choices may include:

- Routine care for resected head and neck squamous cell carcinomas with intermediate pathologic risk features.
- Joining a different research project.
- The procedure or drug offered to you may also be available without being in any research project.

The research doctor can explain both the possible benefits and the risks of other options that are available to you.

D4. WILL I BE GIVEN NEW INFORMATION ABOUT THE PROJECT?

If we learn any important new information about the study intervention (hypofractionated radiotherapy) that might change your mind about being in the project, we will tell you about it right away. You can then decide if you want to stay in the project.

D5. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THE PROJECT?

Emergency medical treatment for injuries directly related to your participation in this research project will be provided to you. You or your health insurance will be billed for the costs of this emergency treatment. MCW will decide on a case by case basis if they will reimburse you or your insurer for emergency treatment costs. If your research-related injury requires medical care beyond this emergency treatment, you or your insurer will be responsible for the costs of this follow-up care.

At this time, there is no plan for any additional financial payments.

If you believe that you have been injured because of your participation in this project, contact the research doctors right away. Contact information: Musaddiq Awan, MD, 414-805-6700.

Nothing in this consent form affects any legal rights you may have nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence.

D6. WHO CAN ANSWER MY QUESTIONS ABOUT THE PROJECT?

- If you have more questions about this project at any time, you can call Musaddiq Awan, MD at 414-805-6700.

- If you have questions about your rights as a research participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

E. PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION

E1. What health information will be collected and used for this project?

To be in this research project, the research team needs your permission to access, collect and use some of your health information. If you say no, you cannot be in the project. This information may come from questions we ask, forms we ask you to fill out, or your medical record, as described below. We will only collect and use information needed for the project.

The protected health information (PHI) originates from services you will or have received at one or more of the following locations: the Medical College of Wisconsin (MCW); Versiti, Inc.; Children's Hospital of Wisconsin (CHW); any Froedtert Health Affiliate- Froedtert Hospital (FH), Inc.; Froedtert Menomonee Falls Hospital; Froedtert West Bend Hospital; Froedtert & The Medical College of Wisconsin Community Physicians Clinics, Inc. (FMCWCP); the West Bend Surgery Center, LLC; and the Froedtert Surgery Center, LLC.

The health information to be collected and used for this project is:

- Past and present medical records to document relevant pre-existing conditions
- Records about your study visits and results of tests done during the study
- Records about phone calls made as part of this research
- Research records

E2. Who will see the health information collected for this project?

The only MCW/Froedtert Hospital employees allowed to handle your health information are those on the research team, those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the hospital's rules are followed.

If the costs of any necessary emergency medical treatment in the event of a research-related injury are billed to your health insurance, your health information may need to be disclosed to the insurer for billing purposes.

The research team may share your information with people who don't work at MCW/Froedtert Hospital because they planned, pay for, or work with us on this project. The federal Privacy Rule may no longer protect your health information once it leaves MCW/Froedtert Hospital. For this project, we plan to share information with those doctors, researchers or government representatives working with us on this project at the institutions or companies listed here:

- Florence Healthcare, Inc.;
- Government agencies in the U.S., such as the Food and Drug Administration (FDA), National Cancer Institute (NCI), and National Institutes of Health (NIH);
- Other federal and state agencies, such as the Office of Human Research Protections, (OHRP);
- Others required by law who monitor research

Because this project involves the use of drugs and/or devices, the FDA also has the right to inspect all project records.

We may record your research information, including results of tests and procedures done for research, in your Froedtert Hospital and/or Medical College of Wisconsin medical record. As a result, this research information may be seen by people allowed to see your medical records for healthcare operations or treatment, by those you allow to see your medical records by giving written permission, and by others when required by law.

We will not use your personal health information for a different project without your permission or the permission of a hospital research review board (IRB). Once all personal identification is removed from your health information, the information may be used for future research or distributed to another investigator for future research without additional informed consent from you or your legally authorized representative. The information might also be used or released for other purposes without asking you. Results of the project may be presented in public talks or written articles, but no information will be presented that identifies you.

E3. What are the risks of sharing this health information?

One risk of taking part in a research project is that more people will handle your personal health information collected for this project. The research team will make every effort to protect the information and keep it confidential, but it is possible that an unauthorized person might see it. If you have questions, you can talk to the research doctor about whether this could apply to you.

E4. How long will you keep the health information for this project?

If you sign this form, we plan to keep your information without any end-date in case we need to check it again for this project.

E5. Can I cancel my permission to share this health information?

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to Musaddiq Awan, MD at:

Department of Radiation Oncology
Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee WI 53226

The letter must say that you have changed your mind and do not want the researcher to collect and share your health information. At that time, we may decide that you cannot continue to be part of the project. We may still use the information we have already collected.

E6. Access to records

You may not be able to see, or copy, your project-related health information until after the project has been completed; otherwise, it could affect the study.

F1. FOR MORE INFORMATION ABOUT THE PROJECT

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.

You can look up this project by referring to the ClinicalTrials.gov number (NCT05120947) or by asking the research team for a printed copy.

CONSENT TO PARTICIPATE

By signing my name below, I confirm the following:

- I have read (or had read to me) this entire consent document.
- All of my questions have been answered to my satisfaction.
- The project's purpose, procedures, risks and possible benefits have been explained to me.
- I agree to let the research team use and share the health information and other information gathered for this project.
- I voluntarily agree to participate in this research project. I agree to follow the procedures as directed. I have been told that I can stop at any time.

IMPORTANT: You will receive a signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.

Subject's Name *please print*	**Subject's Signature**	**Date**
Name of Witness, if applicable *please print*	**Signature of Witness**	**Date**

Rationale for Use of Witness	
☐ Subject has limited/no literacy ☐ Subject has limited English proficiency ☐ Subject has limited/no vision	☐ Sponsor requirement ☐ Other _____

*** Name of person discussing/ obtaining consent** *please print*	**Signature of person discussing/obtaining consent**	**Date**

** A member of the research team trained and authorized by the Principal Investigator to act on her/his behalf in obtaining informed consent according to the protocol. The Principal Investigator is responsible and accountable for the research project.*