Subject Information and Consent Form

Phase II non-randomized Trial of Stereotactic Ablative Radiotherapy (SABR) for Oligometastases

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Name of Granting Agency: None

For emergencies only: Call the centre nearest you and ask for your study doctor or, if he or she is not available, ask for your usual oncologist or the oncologist on-call.

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Vancouver Island Centre	(250) 370-8000
Fraser Valley Centre	(604) 581-2211
Abbotsford Centre	(604) 851-4700
Centre for the Southern Interior	(250) 862-4000
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For non-emergency contact numbers, see section 20 below.

1. INTRODUCTION

You are being invited to consider participating in a clinical study (a type of research study with human participants). Clinical studies (also known as clinical trials) include only participants who choose to take part. Please take your time to make your decision.

This document describes the purpose, procedures, benefits, discomforts and risks associated with this study, as well as your rights if you decide to participate in the study. Before agreeing to participate, it is important for you to understand the study. Feel free to discuss the information in this document with your friends and family and/or your family doctor.

Please ask the study doctor or study staff to explain any words in this document that you don't understand, and make sure all your questions have been answered to your satisfaction before signing this study information and consent form.

You are being asked to take part voluntarily in this study because your cancer has spread to a small number of other parts in your body (i.e. you have metastatic cancer). You have up to 5 different spots where your cancer has spread. When cancer has spread to only at a few locations this is called oligo-metastatic disease.

2. WHY IS THIS STUDY BEING DONE?

This research is being done because it is not known if higher dose precision radiation known as Stereotactic Ablative Body Radiotherapy (SABR) to a limited number of sites of metastatic cancer is tolerated (i.e. has low risk of side effects) and has a positive impact on your survival (i.e.

increases the chances of you living longer) compared to the current standard treatment for oligometastatic disease that can involve chemotherapy, radiation therapy, or best supportive care.

Chemotherapy can cause your disease to shrink, but over time your disease will likely re-grow and spread. In this study we are looking to see if there is a benefit to delivering a high dose of radiation to all your current cancer spots, with the goal to prevent these spots from growing. The benefit may be in terms of delaying or preventing future chemotherapy or potentially it may result in longer survival. Alternatively, there may be no benefit at all, and potential higher side effects due to higher doses of radiation.

The type of radiotherapy, SABR, is a newer method of radiation treatment that delivers high-dose, precise radiation to small tumors with 1 to 3 weeks of treatment. This new technique can potentially allow radiation treatments to be focused more precisely, and be delivered more accurately than with older treatments. The potential benefits of SABR in this setting are that it could reduce side effects and/or improve the chance of controlling the cancer by more accurately treating the cancer and by giving higher doses of radiation. SABR is considered a standard treatment for small lung cancers, and selected cancers that have spread to the brain, but its value for patients with oligo-metastatic cancer is not known.

The purpose of this study is to evaluate how long patients live after SABR treatment of oligometastatic disease, what side effects they experience, how SABR impacts on their quality of life, and how long it is before they start or re-start chemotherapy.

3. WHO IS CONDUCTING THIS STUDY?

This study is not receiving funds from an external agency or sponsor. This study is being conducted by oncologists at the BC Cancer.

4. HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

This study will accrue 400 patients.

5. WHO CAN PARTICIPATE IN THIS STUDY?

You may be able to participate in this study if:

- You are age 18 or older
- You are able to do light activities
- You are able to provide informed consent
- You are willing to complete the questionnaire(s) relating to your tumor sites and other assessments that are a part of this study, via paper or online using REDCap, if you provide your email on this consent form.

- You have been diagnosed with oligometastatic disease which has been confirmed by imaging or a biopsy

- Your oncologist thinks you are healthy enough to receive the treatments in this study

- You have a maximum of 5 metastases that can be treated

- Your metastatic lesions should not have been previously treated with SABR

- You have met all applicable screening eligibility criteria (i.e CTs, bone scan, MRI, PET-CT and blood tests where applicable) within 14 weeks prior to SABR treatment

- All of your metastatic lesions cannot be removed surgically

- You are not receiving chemotherapy or systemic therapy for the period of commencing 2 weeks prior to your first radiation treatment through to 1 week after your last radiation treatment

6. WHO SHOULD NOT PARTICIPATE IN THE STUDY?

You cannot participate in this study if:

- You have a medical condition that would prevent you from receiving radiation treatment

- You have a metastatic lesion in your femoral (thigh) bone and risk of fracture is high

- You have 1-3 metastatic lesions in your brain and nowhere else

- You have received previous SABR treatment to your metastatic lesions

- You have spinal cord compression as seen from radiological or clinical evidence

- You have persistent cancer related fluid around your lung

- It is not possible to treat all of the areas of cancer you have in your body

- You have brain metastasis requiring operation by a neurosurgeon

- You are a woman who is pregnant or lactating

7. What Is Involved In Participating In The Study?

Please see the Study Plan attached to the end of this consent form (-section 9).
All participants in the study will receive Stereotactic Ablative Body Radiotherapy (SABR). After the SABR is finished, you may still receive chemotherapy, surgery or other cancer treatments at the discretion of your doctor(s).

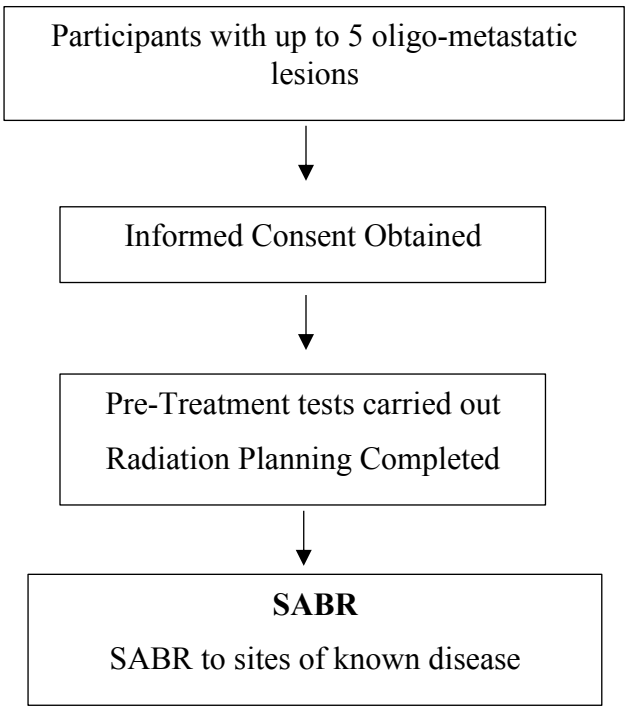
8. Study treatment:

The number of treatments and timing of the SABR delivery depends on the location of your cancer spots. At times several spots can be treated at the same time and at times your doctor(s) will choose to finish the treatment of one spot before starting the treatment of the next spot.

9. Procedures and medical tests

STUDY PLAN

Another way to find out what will happen to you during the study is to read the study plan below. Start reading at the top and read down the list, following the arrows.



FOLLOW-UP

Clinical follow-up with quality of life questionnaire(s) and imaging as required at visit 6 weeks- 3 month, 6 month and then every 6 months for 5 years.

Screening Procedures/Tests:

The following tests will be done at the BC Cancer to make sure that you are eligible to participate in this study. These exams, tests or procedures are part of regular cancer care and may be done even if you do not participate in the study. If you have had some of them recently, they may not need to be repeated. Depending on the results, there is a possibility that you will not be eligible to participate in the study:

- Blood tests – as determined by your study doctor
- History and physical examination by your oncologist or study doctor.
- Pregnancy test for women of child-bearing potential
- Computed tomography (CT) scan or magnetic resonance imaging (MRI) or bone scan of metastatic disease sites – A CT scan is a series of x-rays of the body from many angles that are turned into 3-dimensional pictures on a screen. CT scans often involve injecting a dye into your vein. A MRI is an imaging technique that uses a strong magnet to produce pictures of areas inside the body. MRI is useful for assessing organs and other soft tissue, such as the inside of bones. Bone scan (picture) of the bones in your body, which is a test that can find cancer that has spread to the bones.
- Full body CT Scan/PSMA-PET/PET scan: A PET scan is used to try to find small deposits of cancer that can't be detected on CT scans. It involves injecting a small amount radioactive sugar into your vein, and this sugar is taken in by cancer cells. The location of the sugar in the body tells your doctor where cancer cells might be. This may not be required for this clinical study.
- Biopsy – A biopsy is a procedure to take a sample of your tumor. You must have had at least one biopsy confirming that you have cancer, but this may have been done in the past at the location where your cancer started. It is also an option to have a biopsy of the cancer that has spread, which will be treated with SABR, though it is not necessary. This will be decided between you and your oncologist or study doctor.

If you are eligible to participate in the study, many of these tests will be repeated during the study. These are common tests but some of them might be done more often than if you were not taking part in this research study. If you are not eligible for the study, you will proceed with standard of care. Your health records will not be collected for the study, and any copies collected for the study will be shredded. The originals will only exist within your clinical chart for clinical care.

Treatment Procedures:

Stereotactic ablative radiotherapy (SABR)

You will receive Stereotactic Ablative Body Radiotherapy to all sites of metastatic cancer.

The radiation planning process may involve construction of a plastic mask or special bean-bag device to hold your head or body still for treatment followed by a CT scan. For some lung tumors, there is often a compression device on the abdomen that prevents you from breathing deeply. The information from the CT scan will be used to target the tumor and minimize the dose to normal tissues.

Treatments will be given either daily or every other day, on weekdays, over 1-3 weeks, depending on the location of your metastatic cancer. A CT scan of the region being treated will be taken on the radiation unit prior to treatment each day and your position for the treatment adjusted if necessary. Once your positioning is confirmed, the treatment will be given.

Questionnaires:

You will be asked to fill out questionnaire(s) before starting the study, at the 6 week- 3 month visit, 6 month visit and then every 6 months until 5 years after start of treatment, to understand how your treatment and illness affect your quality of life. You can either complete the questionnaires when you come in for your appointment, or you can complete them at home, online using REDCap, or on paper. You are not required to answer any questions that you are not comfortable answering. The number of questionnaires you will complete will depend on the number of metastatic lesions found. For example, if you have 1 bone met, you will fill out a POSI-Bone questionnaire at your visits. If you have 3 different metastatic spots, you will need to fill out 3 different questionnaires.

Site of Tumor	Questionnaire name
Adrenal	FACIT-AD
Bone	POSI-Bone
Central Nervous System (CNS)	POSI-CNS
Head and Neck	POSI-HN
Lung/ chest	POSI-Lung
Lymph Nodes	Dependent on location (POSI-Bone, FACIT-AD, etc)
Pelvis (Female)	POSI-Female Pelvis

Pelvis (Male)	POSI-Male Pelvis
Soft Tissue Organs (e.g. Liver)	FACIT-AD

These questionnaires will ask how you are feeling physically and mentally and will take about 10 minutes each to complete. Some of the questions are personal; you can decide not to answer these if you wish. The information you provide is for research purposes only and will remain strictly confidential, as explained later in this form**.** You will be identified on the questionnaire by a study number, coded initials and your partial date of birth and not by any personal information such as your name.

Summary of Treatments, Tests and Procedures

Screening Evaluations

Day	**Tests and Procedures**
Prior to starting treatment	History and Physical exam, blood tests as needed, pregnancy test (for women of childbearing potential) CT scan or MRI scan full body CT scan/PSMA-PET/PET scan

Study Treatment

Day	**Tests and Procedures**
Day 1	Planning CT to design radiation treatment
Approximately Day 14	Start radiation treatment Radiation schedule will be, given either daily or every other day, on weekdays, over 1-3 weeks, depending on sites of tumor being treated

Follow-up Evaluations

Day	**Tests and Procedures**

6 week- 3 month and 6 month	Follow-up (in person or remotely) appointment with your study doctor, physical examination by your study doctor (or family doctor if appointment is over videolink/ phone as needed) and complete questionnaire. An assessment of any side effects you may be having. CT scan and/or other imaging (MRI, PSMA-PET/PET or bone scan) as required by doctor
Subsequently, Every 6 months for 5 years	Follow-up (in person or remotely) appointment with your study doctor, physical examination by your study doctor (or family doctor if appointment is over videolink/phone as needed) and complete questionnaire. An assessment of any side effects you may be having. CT scan and/or other imaging (MRI, PSMA-PET/PET or bone scan) as required by doctor

The additional time needed beyond your regular follow-up is approximately 10-15 minutes per clinical visit with the doctor and 10 minutes per questionnaire at each visit. Imaging tests should be similar to standard of care.

1. What Are my Responsibilities?

It is important that you notify your study doctor of any side effects you experience and any new medications you plan on taking.

2. How Long Will You Be In The Study?

SABR will last for about 1 to 3 weeks, depending on the location of your metastases. Follow-up evaluations will be performed at visit 6 week-3 month, 6 month and then every 6 months for 5 years by your study doctor. The follow-up schedule and evaluations in the study would be similar to what you would receive if you were treated outside the study for oligo-metastatic disease.

The researchers can take you off the study treatment early for reasons such as:

- The treatment does not work for you and your cancer comes back or gets worse.
- You are unable to tolerate the study treatment
- You no longer wish to participate.
- New information shows that the study treatment is no longer in your best interest.
- Your study doctor no longer feels this is the best treatment for you.

Even if you stop treatment early, we would like to keep track of your health for the next 5 years to look at the long-term effects of the study treatments. Patients who receive SABR at the BC Cancer

typically are followed for 5 years by their oncologist, which we will also do within this study. If you participate in this study, we will follow you at visit 6 week-3 month, 6 month and then every 6 months for 5 years after treatment, which may be more frequently than is standardly performed at the BC Cancer, as most oncologists follow patients every year for 5-6 years after SABR. We will follow-you up either in person or over videoconference call (also known as videolink).

3. What Are The Risks Of The Study?

While on the study, you are at risk for the side effects listed below. You should discuss these with your study doctor. As with any treatment additional unexpected and sometimes serious side effects are a possibility. In addition, there is a possibility that the study treatment on study could delay other treatments, such as chemotherapy, since chemotherapy cannot be delivered at the same time as SABR. It is unknown if this could be harmful to you, but it is possible that you could have a chemotherapy delay or even miss a chance to receive chemotherapy for a number of reasons, such as a decline in your health or no measurable tumor to monitor.

Your study doctor will watch you closely to see if you have side effects. Sometimes medications will be given to you to make side effects less serious and uncomfortable. Many side effects go away shortly after treatment is stopped but in some cases side effects can be serious, long-lasting or permanent.

If you experience serious side effects that require treatment between regular BC Cancer visits, it is important that you make every effort to return to the BC Cancer where your treatment was given. If you need immediate treatment and are unable to return to the BC Cancer where you received your treatment, you should go to the nearest Emergency department and your study doctor should be contacted as soon as possible.

Risks from Radiation

You will undergo a CT scan, called a “simulation”, to design the radiation. This CT scan is considered standard for radiation treatment and exposes you to a small amount of radiation. Some participants find the CT scanning table uncomfortable, and in some cases a mild painkiller (e.g. Tylenol) is given for those participants.

Risks and side effects related to radiation therapy depend on the area being treated. For example, for a participant receiving radiation to the brain, the side effects related to the lungs and bowels do not apply. Risks and side effects related to radiation are listed below.

Very likely [Common] (*21% or more, or higher than a 1 in 5 risk)*:

- Fatigue
- Skin Rash in area being treated
- Hair loss in area being treated

Less likely [*Occasional*] (*5 to 20% or between a 1 in 5 and 1 in 20 risk*):

- Nausea/vomiting
- Decreased hearing or irritation of the ears
- Dryness or irritation of the eyes (if an area near the eyes is treated) Dry or sore mouth or throat or loss of taste during radiation treatments.
- Temporary lung injury resulting in shortness of breath or cough (if the lungs are being treated)
- Temporary difficulty or painful swallowing (if the neck or central chest is being treated)
- Diarrhea or cramping of the bowels (if the abdomen or pelvis are treated)
- Bile duct blockage and yellowing of skin or jaundice (if the abdomen is treated)
- Discomfort or frequency of urination (if the pelvis is treated)

Rarely (*1 to 4% or between a 1 in 25 and 1 in 100 risk*):

- Permanent lung injury resulting in shortness of breath or cough (if the lungs are being treated)
- Bone injury resulting in a specific broken bone (if that bone is being treated) Changes in thinking or memory (if the brain is treated).
- Persistent cramping, diarrhea or bleeding from the bowel (if the abdomen or pelvis is treated)
- Persistent frequency or discomfort with urination (if the pelvis is treated)
- Persistent pain in a bone, muscle, or nerve

Rare but Serious *(less than 1% or less than a 1 in 100 risk)*:

Radiation treatments are associated with a small risk of serious injury to tissues or organs that are included in the area being treated. This injury may show up months to years post treatment. In very rare instances, these side effects may result in death. Some of these side effects include (depending on whether these areas are being treated):

- Brain injury resulting in loss of strength, sensation or thinking ability
- Spinal cord injury resulting in paralysis of the lower half of the body including both legs
- Esophagus injury resulting in difficulty swallowing
- Heart injury resulting in a heart attack or fluid collection on the heart

- Stomach ulcer or stomach injury resulting in bleeding or perforation (hole) or fistula (abnormal connection between the bowel and another organ)
- Rectal or bowel injury resulting in bleeding or perforation (hole) or fistula (abnormal connection between the bowel and another organ)
- Bladder injury resulting in bleeding or perforation (hole) or fistula (abnormal connection between the bowel and another organ)
- Development of a second cancer in the radiation area, usually more than 5 years after treatment.
- Adrenal dysfunction resulting in adrenal insufficiency or inadequate production of hormones by the adrenal gland, producing symptoms such as fatigue and muscle weakness.
- Tissue injury resulting in avascular necrosis or death of bone tissue from lack of blood supply. Symptoms include joint pain and limited range of motion.

Your physician will monitor your therapy and make adjustments to your treatment or prescribe medicines in order to manage side effects that occur during treatment. The radiation technique, daily dose and total dose of radiation for your treatment will be prescribed by your physician in order to minimize the chance of late serious injury as outlined above.

It is possible, although unlikely, that SABR may be associated with unexpected side effects that are not yet known or included on this list. For example, when SABR was first implemented, treatment of tumors in the centre of the chest were associated with a high risk of injury to the breathing passages (bronchi), and so the doses delivered to tumors in that area have been lowered to reduce that risk.

Reproductive Risks

The procedures used in this study might be harmful to a fetus. If you are a woman and can have children, you will need to have a pregnancy test before enrolling in the study to be sure that you are not pregnant. If you are pregnant, you cannot participate in this study. You must not become pregnant or father a baby while on this study and for 6 months afterward because the treatment or procedures used in this study might be harmful to a fetus. Your study doctor should discuss methods with you to ensure that you do not become pregnant or father a baby during the study. Your study doctor will be able to inform you of methods that are safe to use while on this study. If you do become pregnant during the study or if you father a child during the study you should immediately notify your study doctor.

The risk to your partner and the fetus is unknown. If your partner becomes pregnant, she will be asked to sign a consent form to allow access to information on the outcome of her pregnancy. If your partner does not consent to this, it will not affect your continued involvement in the study.

Radiation from Follow-up tests (e.g. CT scans)

Participants will be exposed to a small amount of radiation from a CT scan. The amount of additional radiation exposure is very small compared to the amount of radiation used for treatment of your tumor, and poses minimal risks. This is would be done the same as standard of care.

4. Are There Benefits To Taking Part In The Study?

If you agree to take part in this study, there may or may not be direct benefit to you. Your cancer may shrink but these things cannot be predicted for you. The information learned from this study may or may not help other participants with metastatic cancer and oligo-metastatic disease in the future.

5. What Other Options Are There?

If you decide not to take part in this study, you should discuss other treatment options with study doctor. These may include:

- **Chemotherapy (or systemic therapy)**
  - Depending on your underlying cancer, there may be many or just a limited number of chemotherapy treatments. Also, you may or may not have received chemotherapy prior to entering into the study. As a result of the wide range of possibilities, all study participants are urged to discuss their specific chemotherapy / systemic therapy options with their medical oncologist.
- **Palliative radiation therapy**
  - This is generally a lower dose of radiation then SABR and is given daily over 1-2 weeks with the aim of reducing symptoms. The dose is typically not high enough to completely kill the cancer at the site being treated.
- **Best supportive care**
  - This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Best Supportive care tries to keep you as active and comfortable as possible.

Please talk to your study doctor about the known benefits and risks of these or other treatment options. Your study doctor can also discuss with you what will happen if you decide not to undertake any treatment at this time.

6. What About Confidentiality?

If you agree to participate in this study, the study doctor and his/her study team will look at your personal health information and collect only the information they need for this study. "Personal health information" is health information about you that could identify you because it includes information such as your name, address, telephone number, date of birth, new and existing medical records or the types, dates and results of various tests and procedures. The personal health information collected in this study may include:

- Your medical history including any medications you are taking
- Your test results (e.g., blood tests)
- Your x-rays, CT, MRI scans or other body scan reports, and
- Reports about your treatment and side effects

Your confidentiality will be respected. However, qualified representatives of the following organizations may also look at your personal health information to check that the information collected for the study is correct; to confirm your response to treatment, or to make sure the study followed proper laws and guidelines:

- The BC Cancer the centre coordinating this study
- The UBC BC Cancer Research Ethics Board, the research ethics committee that oversees the ethical conduct of this study at the BC Cancer.

In addition, these representatives may receive health information about you that is collected specifically for this research ("study data"). However, to protect your identity, any study data about you that is sent outside of the BC Cancer will not contain personal identifiers such as your name, address or BC Cancer ID number. Only a unique study code number will be on any documents sent outside the BC Cancer.

The study doctor, his/her study team and the organizations listed above will keep the information they see or receive about you confidential, to the extent permitted by applicable laws. Though there is a risk of you being identified, we have taken reasonable steps to minimize this risk. The study doctor will keep any personal health information about you in a secure and confidential location for a minimum of 25 years. A list linking your study number with your name will be kept by the study doctor in a secure place, separate from your study file.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to insure that your privacy is respected and also give you the right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor. You have the right to see and copy your personal health information from your BC Cancer records. However, your study data will not be available for your review. This is to ensure the scientific integrity of the study. Researchers are required to keep personally identifiable information confidential.

Your month/year will also be provided if requested by the responsible regulatory agency.

Although you may not be aware of this fact, emails sent to some webmail services (e.g. Gmail, Hotmail, etc.), may be stored/routed outside of Canada (for example, in the United States). Due to the fact that future emails contain personal information about you, including your name, the Freedom of Information and Protection of Privacy Act requires that we obtain your consent before

we continue. If you choose not to consent, you will not be able to access REDCap. Providing your email means that you voluntarily agree and give your consent for BC Cancer to use your personal email for these services.

Email address: _____

You may withdraw your permission to use your personal health information at any time by letting the study doctor know, and the study doctor will then no longer collect or share your personal health information in connection with the study. However, if you withdraw your permission, you also withdraw from the study.

If you withdraw from the study, the information or study data that was collected from you before you withdrew will continue to be used. The study doctor will continue to send study data to the study coordinating centre that is essential to ensure that the study is scientifically reliable, unless you also withdraw your permission to do so.

When the results of the study are published or presented, your name will not be used and no information that could identify you will be released. It is expected that the study results will be published 1-2 years after the study is completed. Your study doctor will be informed of the results of the entire study (not your individual results) once they are known and you may ask your study doctor to share the results with you.

The original signed consent form will be included in your health record/BC Cancer chart.

Primary Care Physician(s) /Specialist(s) Notification

Your family doctor will be informed that you are taking part in a study. This is done to allow them to help you make informed decisions about your care.

7. What Are The Costs?

The study treatment will be provided to you free of charge while you are participating on this study.

Reimbursement

As part of your participation in this study, you may incur additional expenses. For example, you will be required to come to the BC Cancer for treatment over a period of 1-3 weeks. This may result in increased parking or transit expenses. You will not be reimbursed for this study related expenses.

Remuneration

You will not be paid for participating in this study.

8. What Are Your Rights As A Participant?

Taking part in this study is voluntary. You may choose not to take part. If you decide to take part, you may leave the study at any time. Deciding not to take part or deciding to leave the study later will not affect the care you receive, nor will it result in a loss of benefits to which you are otherwise entitled. If you are thinking about withdrawing from the study, you should talk to your study doctor before you make your final decision. If you withdraw, your study doctor will discuss further treatments with you and continue to treat your cancer with the best means available.

If you are injured as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost. However, no funds have been set aside to compensate you for such things as lost wages, disability or discomfort due to this type of injury.

By signing this form you do not give up any of your legal rights against the investigators, institutions involved, or anyone else, and you do not release the study doctors or participating institutions from their legal and professional responsibilities.

9. What Are Your Protections As A Participant?

You will be told, in a timely manner, about new information that may affect your health, welfare, or willingness to stay in this study.

A Data Safety Monitoring Committee, a group of experts who are independent of the study will be reviewing the data from this research throughout the study to see if there are unexpected or more serious side effects than described in this form.

10. Conflict Of Interest

The BC Cancer is not receiving any funds to help offset the costs of conducting this research. The doctor treating you may be the doctor in charge of the study.

11. Whom Do You Call If You Have Questions Or Problems?

If you have questions about taking part in this study or if you suffer a research-related injury you can talk to your study doctor, or family doctor. If you suffer a study-related injury you should immediately talk to your study doctor, or if he or she is not available the oncologist on call. Your study doctor is:

_____	_____
Name	Telephone

24-hour contact number: _____

Or, you can speak to the doctor who is the principal investigator, Dr. Rob Olson, at 250-645-7325.

Or, you can speak to the Head of the Radiation Therapy Program of the BC Cancer. That person can be reached at 604-877-6000.

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598).

17. SIGNATURES

SUBJECT CONSENT

You will be given a copy of this consent form after it has been signed and dated by you and the study staff.

My signature on this consent form means the following:

- The study has been fully explained to me, I have had sufficient time to consider the information provided and to ask for advice if necessary,
- I have had the opportunity to ask questions and have had satisfactory responses to my questions,
- I have read and understood each page of this subject information and consent form,
- I am aware of what is required of me as a participant in the study,
- I am aware of the risks to me of participating in the study and the risks to the fetus if I become pregnant or father a child during this study,
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific objectives,
- I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time without changing in any way the quality of care that I receive,
- I authorize access to my personal health information and study data as explained in this consent form,
- I understand I need to provide my email address if I choose to complete the questionnaires online using the REDCap system.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form,
- I understand that there is no guarantee that this study will provide any benefits to me, and
- I voluntarily consent to participate in this study.

Please check the box below that applies to you:

☐ I am a newly enrolling subject and, by signing below, indicate that I consent to participate in this study.

☐ I am already enrolled in this study. By signing below, I acknowledge that I understand the new or changed information contained within this revised version of the consent form, which has been pointed out and explained to me, and I am willing to continue to participate in this study.

Name of Participant (print)	**Signature of Participant**	**Date** (dd-mmm-yyyy)

Person Obtaining Informed Consent:
My signature below signifies that I have explained the nature and purpose of the study and the risks involved to the study participant, and I have answered all questions to the best of my ability.

Name of Person Obtaining Informed Consent (print)	**Signature of Person Obtaining Informed Consent**	**Date** (dd-mmm-yyyy)

If this consent process has been done in a language other than that on this written form, with the assistance of an interpreter/translator, indicate:

Language:_____

Was the participant assisted during the consent process? ☐ ***YES*** ☐ ***NO*** *If **YES**, please check the relevant box and complete the signature space below:*

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and appeared to be understood by the participant (please check if subject is unable to read).

☐ The person signing below acted as a translator for the participant during the consent process (please check if an interpreter/translator assisted during the consent process).

Name of Person Assisting in the Consent Discussion (print)	**Signature of Person Assisting in the Consent Discussion**	**Date** (dd-mmm-yyyy)