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PROVIDENCE
Cancer Center

## CONSENT FORM FOR A RESEARCH STUDY

**TITLE:** Phase II Randomized Study of High Dose Interleukin-2 Versus Stereotactic Body Radiation (SBRT) and High Dose Interleukin-2 (IL-2) in Patients with Metastatic Melanoma (PHS IRB # 11-062A)

**PRINCIPAL INVESTIGATORS:** Brendan Curti, MD, Steven Seung, MD, PhD and Marka Crittenden, MD, PhD.

**SPONSOR:** Earle A. Chiles Research Institute (EACRI)

### INTRODUCTION AND PURPOSE:

You are being asked to take part in a clinical trial. Clinical trials are a type of research study designed to find better ways to treat diseases, like cancer. This consent form will explain this research study to you and help you decide if you want to take part. Please read this information carefully and ask as many questions as you like before deciding if you want to take part.

You are being asked to take part in this study because you have melanoma (a type of skin cancer) that has spread to other parts of your body and is difficult to treat.

Standard treatment for melanoma is immunotherapy that helps the immune system fight the cancer cells or chemotherapy, which kills dividing cancer cells. High-dose Interleukin-2 (IL-2) is an immunotherapy drug that is approved by the Food and Drug Administration (FDA) as a standard treatment for metastatic melanoma or kidney cancer. IL-2 is a natural substance in the body that affects the body's immune system by helping some white blood cells (called lymphocytes) to kill tumor cells. The IL-2 given to patients for cancer is made in a laboratory.

Radiation therapy kills tumor cells and is used to treat many kinds of cancer. However, researchers are also finding that when tumor cells are killed from radiation, substances are released that increase the activity of the immune system and helps it to better fight cancer cells.

An earlier study done here at Providence Cancer Center in a small number of patients with metastatic melanoma or kidney cancer showed that giving high-dose IL-2 and radiation was active against the cancers, so this needs to be tested further in a larger number of patients.

This study will compare the effects (both good and bad) of high-dose IL-2 given by itself compared to high-dose IL-2 and radiation therapy. Research tests will also be done on blood samples to study immune function and response to the treatments.

The radiation therapy given in this study is called stereotactic body radiotherapy (SBRT). SBRT is able to deliver a higher-dose of radiation to a tumor site than standard radiation therapy, so fewer treatments are needed.

Although neither of these treatments is investigational, there has not been much research into how

effective they are when given together.

Half of the patients in this study will receive high-dose IL-2, and the other half will receive SBRT and high-dose IL-2. SBRT and another course of high-dose IL-2 will be offered to patients who receive high-dose IL-2 alone without radiation and do not have shrinkage of their melanoma.

This study will enroll up to 44 patients at Providence Cancer Center.

**STUDY PROCEDURES:**

Screening Visit
At the first visit (called the screening visit), your study doctor will see if you qualify to take part in this study. Following are the tests and procedures that will be done at this visit:

- You will have a physical exam and be asked about your health
- Your vital signs (blood pressure, temperature, breathing rate, heart rate) will be measured
- You will have blood drawn for routine safety tests (blood counts -- CBC, organ function (like kidneys and liver), and thyroid hormone)
- You will have a CT scan (uses radiation) to check your tumor(s)
- You may need to have a PET scan (nuclear medicine imaging that requires you to receive a radioactive tracer (contrast material) before the scan)
- You will have an MRI scan of your brain (the use of magnetic field and a computer to produce detailed pictures)
- You will have an ECG (a recording of the electrical activity of your heart)
- You will have breathing tests to check the function or your lungs (called pulmonary function tests, or PFTs)
- You may need to have a heart stress test, which is similar to an ECG done while on a treadmill (if you are over the age of 50 or at risk for heart problems this will be done)
- You will need to have a pregnancy test (if you are a woman who could get pregnant)

If the above screening tests and procedures show that you qualify for this study, and you wish to take part, you will be randomly assigned (by chance, like the flip of a coin), to one of the two treatment arms. Neither you nor your study doctor may choose which treatment you receive:

**Arm A:** SBRT followed by high-dose IL-2

**Arm B:** High-dose IL-2 alone

Study Treatments:
SBRT treatment will be given on a single day (a Friday) for the first 20 patients who join this study. Up to 3 different tumor locations may be treated. If you are assigned to Arm A, treatment with high-dose IL-2 will be started the following Monday. After 20 patients have joined this study, patients assigned to Arm A will receive 2 SBRT treatments (one on Wednesday and one on Friday). IL-2 will start the following Monday.

Before the SBRT treatment(s), you will have a treatment planning (called simulation) appointment, during which special CT scans of your body will be done. These scans will create a movie-like image that will help your doctors see how the tumors move when you breathe, and determine their exact locations. This simulation appointment will be done on a different day than your treatment(s). Just before the actual SBRT treatment(s) a special CT scan will be done to further help target the tumor.

Before you receive the high-dose IL-2, you will need to have a central catheter placed into a large vein below your collarbone or in your neck. A catheter is a very thin tube usually about the size of a needle

inserted through the skin into a vein for giving fluids and medicine. You will need to sign a separate consent form for the placement of the catheter, which will list the risks of its placement.

You will be admitted to the hospital for high-dose IL-2 treatments and will start on a Monday. The high-dose IL-2 is given by vein (IV, as an infusion) over 15 minutes, every 8 hours over a 5-day period called a "cycle." The maximum number of doses given in a cycle is 14. In this study you will have up to 2 cycles of high-dose IL-2, with a 16-day rest in between cycles.

Due to severe side effects from the high-dose IL-2, it is possible that your treatment schedule may be changed and your treatments delayed until you recover. Your study doctor may possibly delay your next treatment for a few days if your blood tests and a physical exam show that you are not ready for your next treatment.

You will need to take antibiotics while the central catheter is in place to try to prevent you from getting an infection. You will also need to take medications that will help lessen the side effects from the high-dose IL-2. These include medications to reduce pain and inflammation, to protect your stomach and prevent diarrhea, to prevent an allergic reaction, and to prevent fluid buildup in your tissues and lungs. Your study doctor will give you a prescription for these medications and explain in detail how to take them before you are admitted to the hospital.

Treatment Schedule:

**Arm A**

| Treatment | How Given | How Often | How Long |
|---|---|---|---|
| SBRT | Radiation therapy | First 20 patients<br>1 treatment given on the Friday before high-dose IL-2 is started | Given on one day |
| | | After 20 patients<br>1 treatment given on Wednesday, 1 on Friday before high-dose IL-2 is started | Given on two days |
| High-dose IL-2 | IV – through a catheter | Every 8 hours on Days 1-5 and Days 22-26 | Each dose is given over 15 minutes |

**Arm B**

| Treatment | How Given | How Often | How Long |
|---|---|---|---|
| High-dose IL-2 | IV – through a catheter | Every 8 hours on Days 1-5 and Days 22-26 | Each dose is given over 15 minutes |

Patients on Arm A or Arm B whose cancer stays the same or gets better after the first two cycles of high-dose IL-2 will be able to receive up to 4 more cycles (6 total).

Patients on Arm B whose cancer gets worse after two cycles of high-dose IL-2 will be able to receive SBRT followed by up to 4 more cycles (6 total) of high-dose IL-2.

Routine Tests During Treatment:
You will have regular follow-up visits with the study doctor while you are receiving treatment. In addition, you will have tests to make sure it is safe for you to continue to be in this study and to see if the study treatment is working. All of the tests and procedures listed below are part of your regular cancer care.

On the days of your SBRT treatment (Arm A), you will have the following tests:

- You will have a physical exam and be asked about your health
- Your vital signs will be measured
- You will have blood drawn for routine tests (only on the first day of radiation treatment)

On the days of high-dose IL-2 treatment (Arms A and B) you will have the following tests:

- You will have a physical exam and be asked about your health on each day
- Your vital signs will be measured
- You will have blood drawn for routine tests

On Day 8, you will have blood drawn for routine tests.

During week 7 after your study treatment (Arms A and B) you will have the following tests:

- You will have a physical exam and be asked about your health
- Your vital signs will be measured
- You will have blood drawn for routine tests
- You will have a repeat CT scan and/or other scans to follow your melanoma as recommended by your doctor.

**Blood collection for research testing – for all patients:**
In addition to the routine tests described above, you will have blood collected (about 6 teaspoons) for research tests (to check your immune response) at the following times:

- Before your first SBRT treatment (if you are assigned to Arm A)
- Before your first high-dose IL-2 treatment (all patients)
- After your 3rd high-dose IL-2 treatment (all patients)
- On Day 5
- On Day 8 between your two scheduled cycles of high-dose IL-2 (all patients)
- Your study doctor may request additional blood samples (up to 3 more) during each of your high-dose IL-2 treatments

**Optional (not required) biopsy for research testing**
If it can be safely done, we are asking you to have an ultrasound-guided or CT-guided biopsy on one of your tumors before treatment and on Day 8 of the study. These biopsies are optional; you may still take part in this study even if you decide not to have these biopsies. You will need to decide before you are assigned to a treatment arm, and you can indicate your choice at the end of this consent form. Both of these procedures are done as an outpatient. The biopsies do not benefit you; they are being requested so that the researchers involved in this study can better understand how SBRT and high-dose IL-2 are working.

In an ultrasound-guided biopsy, an ultrasound wand is passed directly over a part of the body. The wand uses sound waves to make a picture that is used to guide a needle into the tumor so that a biopsy can be collected.

During a CT-guided biopsy, the CT scanner will create pictures that are used to guide a needle into the tumor so that a biopsy can be collected.

**Follow-up period:**
You will be asked to come to the clinic for follow up every 3 months for 2 years, every 6 months during year 3, and then once a year at years 4 and 5. The purpose of these visits is to check your disease and general condition. After 5 years, you will continue to be followed according to routine care for your

condition. We will request copies of the results of any tests and procedures that you have as part of that care.

On these visits you will have the following tests:

- You will have a physical exam and be asked about your health
- Your vital signs will be measured
- You will have blood drawn for routine tests
- You will have a CT scan
- You may need to have a PET scan
- You may need to have an ECG

If your cancer gets worse, you will be called by the research staff every 6 months to check on your health.

A table of the study procedures is below:

| | | During IL-2 Treatment | | | | | Follow-up | |
|---|---|---|---|---|---|---|---|---|
| **Study Days** | **Screening** | **SBRT -3*** | **Days 1-5** | **Day 8** | **Days 22-26** | **Week 7** | **Follow-up** | **Survival Follow-up** |
| Medical history | X | X | X | | X | X | X | |
| Physical exam | X | X | X | | X | X | X | |
| Vital Signs and weight | X | X | X | | X | X | X | |
| Routine Blood tests | X | X | X | X | X | X | X | |
| Blood tests for research** | | X | X | X | X | | X | |
| Optional tumor biopsy | X | | | X | | | | |
| ECG | X | | | | | | | |
| CT Scan | X | | | | | X | X | |
| PET scan | X | | | | | | X | |
| Breathing tests (PFTs) | X | | | | | | | |
| Brain MRI | X | | | | | | | |
| Pregnancy test | X | | | | | | | |
| Cardiac stress test (if over 50 or at risk for heart problems) | X | | | | | | | |
| Phone call follow-up*** | | | | | | | | X |

* If you are assigned to receive SBRT, it will be given on a Friday, with high-dose IL-2 given the following Monday (if you receive two doses of SBRT, they will be given on Wednesday and Friday before starting IL-2 on Monday).

** Your study doctor may decide to draw an additional research blood sample during your high-dose IL2 treatments

*** If your cancer gets worse, you will be called by the research staff every 6 months to check on your health

**POSSIBLE RISKS:**

There are risks to you if you take part in this study. The treatment used in this study may cause all, some or none of the side effects listed. In addition, unknown side effects may occur. Most side effects go away after the study treatment is stopped; however, some may be serious, permanent, or even cause death.

High-dose IL-2 therapy may result in serious side effects that could be life threatening and lead to admission to the Intensive Care Unit (ICU). Some of the serious side effects include permanent organ damage (including heart attack, kidney or liver failure). Other side effects are discussed in the risks

section below. Because of the seriousness of your disease, we are asking you to carefully consider these risks and how this study treatment may affect the quality of your life.

The side effects listed below were identified when high-dose IL-2 and SBRT treatment were not given together. Receiving SBRT treatment before high-dose IL-2 treatment may make the side effects of either treatment worse, or cause them to happen more often, although this was not observed in a completed pilot study of SBRT and IL-2 and in other patients treated with this combination. SBRT and high-dose IL-2 have only been studied together in a small number of patients; so we have more to learn about the combination. One of the goals of this study is to learn if side effects from SBRT and high-dose IL-2 are more frequent. Receiving two doses of SBRT is not expected to change the side effects that may occur.

**Risks and Side Effects from High-dose IL-2:**

Likely (more than 50 people out of 100)

- Weight gain that can be as much as 20 pounds of fluid. This causes swelling in the arms and legs and fluid in the lungs that can cause severe shortness of breath.
- Fever and chills
- Skin reaction with itching (similar to an allergic reaction)
- Nasal congestion
- Low number of red blood cells (anemia) that may cause weakness and shortness of breath
- Low number of blood platelets that may cause easy bruising and bleeding
- Very low blood pressure that may require IV fluids and medications to raise it to a safe level
- Tiredness
- Mild hair loss
- Nausea and vomiting
- Diarrhea

Common (between 10 and 50 people out of 100)

- Shortness of breath that may require additional oxygen
- Abnormal kidney function blood tests that may indicate damage or injury
- Abnormal liver function blood tests that may indicate damage or injury
- Loss of appetite

Uncommon (between 2 and 9 people out of 100)

- High amount of sugar (glucose) in the blood. Blood sugar levels that remain high over time can damage the eyes, kidneys, nerves, and blood vessels.
- Confusion -- ranging from forgetfulness and disorientation (not knowing where you are, who you or others are) to combativeness and psychosis (loss of contact with reality)
- Blood clots in the lungs which may be life threatening
- Vision changes
- Infection
- Irregular heart rhythm/beats
- Abnormal function of the thyroid gland that can cause an overactive or underactive thyroid. Symptoms include heart pounding (palpitations), and feeling tired or anxious.

Rare (less than 1 person out of 100)

- Extremely high fever
- Heart attack; changes in heart rhythm
- Decreased blood supply to the bowel (intestines) that can cause tissue damage and may require surgery. This may be serious and life threatening.
- Seizures - if you have had seizures in the past, you are at increased risk

- Severe breathing problems that may require the placement of a breathing tube into the air passage (windpipe) and the temporary aid of a machine (called a ventilator) to help breathing. This is caused by a significant and rapid weight gain from fluid. This can be life-threatening.
- Death

**Risks and side effects from Radiation Therapy:**

Likely (more than 50 people out of 100) for radiation to the lungs or liver
- Fatigue, tiredness
- Skin dryness, tenderness and redness, with peeling like a mild sunburn in the area treated

Common (between 10 and 50 people out of 100) for radiation to the lungs
- Hair loss in the area treated
- Shortness of breath
- Inflammation and scarring of the lungs causing a dry cough, low grade fever, and shortness of breath

Common (between 10 and 50 people out of 100) for radiation to the liver
- Inflammation of the liver causing nausea and/or mild abdominal pain
- Abnormal liver function blood tests that may indicate injury or damage

Common (between 10 and 50 people out of 100) for radiation to the lungs or liver
- Lowered number of white blood cells that may increase the risk of getting an infection
- Lowered number of blood platelets that may increase the risk of bruising or bleeding
- Lowered number of red blood cells (anemia) that may cause fatigue and shortness of breath and require blood transfusions

Uncommon (between 5 and 9 people out of 100) for radiation to the lungs or liver
- Inflammation and scarring of the lungs causing shortness of breath that might require the use of oxygen
- Pericarditis (inflammation of the lining around the heart) that may cause decreased heart function
- Myocarditis (inflammation of the heart muscle) that may cause decreased heart function
- Difficulty swallowing caused by irritation to the esophagus (tube that carries food and fluids from the mouth to the stomach). You should avoid spicy foods and alcoholic beverages during treatment.
- Nausea
- Abnormal liver function blood tests that may indicate injure and damage
- Easy fractures to the ribs (if the tumor in the lung is close to the ribs)

Rare (less than 5 people out of 100) for radiation to the lungs or liver
- Collapse of part of the airway (trachea) that may prevent air from getting to the lungs
- Formation of a fistula (an abnormal connection) between the esophagus and the trachea (windpipe) that will require surgery to correct
- Injury to the spinal cord that could cause paralysis and could be permanent.

**Risks and side effects from a Central Venous Catheter:**
Blood clots can form around the IV catheter that is put into your veins. This occurs in less than 2 people out of 100, and can cause arm swelling that may require removal of the catheter(s). Although extremely rare, any clot has the potential to break off into the blood stream (embolize) and travel to other parts of the body. These clots can go to the lungs and cause shortness of breath, and rarely, death.

A central catheter can become infected. Minor infections around the catheter site may require antibiotics and occasionally (less than 5 people out of 100) develop into a more severe infection of the tunnel (where the catheter lies under the skin) or of the bloodstream. These complications may require

hospitalization or intravenous antibiotics and/or removal of the central catheter. The chance of infection depends on how long the catheter stays in -- the most recent estimate is that there are 1.2 infections for every 1,000 days a catheter is in place.

**Risks and side effects from the optional biopsy**
Possible risks of a CT- or ultrasound-guided biopsy depend on the site where the biopsy specimen is collected. The risks include:

- Bleeding and a collection of blood (hematoma) at the biopsy site (This is rare (less than one in 100 patients).
- Infection: at the biopsy site that could require treatment with antibiotics. This is very rare (less than one in 1,000 patients).
- Pneumothorax: Partial or total collapse of a lung that may cause shortness of breath and require treatment with a chest tube to allow the lung to heal. This occurs in about one in 4 patients that have a lung biopsy. It is also a risk during CT-guided biopsies of the liver

**PREGNANCY/NEW FATHER:**
If you are pregnant or breastfeeding, you cannot take part in this study. You may be required to have a blood and/or urine pregnancy test to see if you are pregnant before you begin this study treatment. If you are sexually active, you must take adequate precautions to avoid the possibility of becoming pregnant or fathering a child while in this study. If you become pregnant, or your partner becomes pregnant during this study, you should tell your study doctor immediately.

After you complete this study treatment, check with your study doctor to see when it might be safe to become pregnant or a new father.

**POSSIBLE BENEFITS:**
There are no guaranteed benefits to you for taking part in this study. If effective, this study treatment may shrink your tumor(s), reduce your cancer-related symptoms, improve your quality of life, or prolong your life. However, this is not known at this time.

The information learned from this study may add to medical knowledge that may help other people with melanoma in the future.

**OTHER TREATMENTS:**
You may choose not to take part in this study. Other treatments available to you include:

- Other standard medications for advanced melanoma are ipilimumab, vemurafenib, IL-2 (without enrolling in the study) or dacarbazine.
- Other experimental treatments, if available
- Supportive care (no active cancer treatment) to ease your symptoms and help make you comfortable

Your study doctor will review these with you before you decide to take part in this study.

**GENERAL INFORMATION:**
Taking part in this study is voluntary. If you decide not to take part, it will not affect your treatment or the health care benefits you have. If you decide to take part, you are free to stop at any time without any effect on your medical care, your relationship with your doctor(s) or the Providence Health & Services.

Your study doctor may remove you from the study at any time if he/she thinks it is medically necessary, you have a serious side effect or you do not follow the study plan. In addition, the FDA, the Providence Health & Services Institutional Review Board (IRB – a committee that reviewed this research to protect your rights), or the study sponsors may end this study at any time. If you stop being part of this study, your study doctor or one of the study staff will talk to you about any medical and safety issues.

While on this study, any important new information that may affect your wish to continue taking part will be given to you.

**COSTS:**
You will not be paid to take part in this study.

The research blood tests and optional biopsies will be paid for by this study. Your study doctor and staff will be responsible for making sure these tests and procedures are billed to this study and not you or your insurance or Medicare. High-dose IL-2 is FDA-approved for the treatment of melanoma and will be billed to your insurance.

You are responsible and must pay for the costs of your routine medical care and medications; however, most major insurance companies or Medicare may cover these costs, at least in part. All other study treatments, medications, tests, and procedures in this study that are considered standard care will be billed to your insurance company in the usual way.

**LIABILITY:**
If you are injured or have an unexpected side effect as a direct result of taking part in this study, all the necessary medical facilities are available for treatment of your injury as is reasonably possible.

Providence Portland Medical Center will pay reasonable costs of medical treatment (doctor's fees and medical expenses) for an injury caused by your study treatment. This treatment for an injury must be approved by your study doctor, and PPMC (the sponsor) must know that your study doctor followed the study plan. You should call your study doctor if you feel you have a research-related injury.

You do not give up any of your legal rights by signing this consent form or taking part in this study.

**PRIVACY:**
Your medical and study records are personal and private and only your study doctor, you and anyone you allow have the right to look at your records. It is important for the research staff, the FDA, the Center for Medicare and Medicaid Services (CMS), the Providence Health & Services Institutional Review Board (IRB – a committee that reviews research to protect your rights), and employees and research staff at the Providence Cancer Center be able to look at your medical and study records. When you sign this consent form, you agree to allow this. If results of this study are reported in medical journals or at meetings, your identity will remain secret.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) gives you certain rights to protect the privacy of your medical information and records. Under HIPAA, you must give your permission before anyone uses or shares your medical information. This information is also called protected health information (PHI). Your rights, as well as the reasons for using your PHI, are described below.

Providence Cancer Center employees and research staff and your study doctor will need to use your PHI for this study. Your study doctor will record PHI about you on study forms that are given to the sponsor. This includes your name, address, telephone number, date of birth, past medical records and the results of tests and procedures done during this study.

By signing this consent form, you agree to allow your study doctor and the research staff to use and share your PHI for the following reasons:

- Make decisions about your medical care
- Evaluate the results of this study
- Make conclusions about the study results

- Provide study results to other study doctors
- Re-evaluate study results in the future, as needed
- Include your study information with results from other similar studies
- Send study information to government health agencies (for example, to the FDA to request approval of the treatment used in this study); this may also include government agencies in other countries
- Report side effects to the FDA and other government agencies
- Send study information to representatives of the study sponsor
- Any other purposes as described in this consent form.

If you are not willing to allow your PHI to be shared, you will not be able to take part in this study.

The study sponsor will receive a code number that identifies your medical records. However, the study sponsor and their representatives, the IRB and any regulatory agencies may review your medical records and make copies. The reasons this might happen is to make sure this study is being done properly, study information is being collected correctly, and for other purposes allowed by law.

Once your PHI is shared with others, it is no longer protected by HIPAA law. However, it will be kept as confidential as possible.

Your permission to use and share your PHI will not end unless you change your mind. You may cancel your permission at any time by sending a written notice to your study doctor. Your PHI for this study will no longer be used or shared. In some circumstances, your study doctor will need to use or share your PHI to continue this research study.

If you cancel your permission, you will no longer be able to take part in this study. The sponsor will still use any PHI they received before you cancel your permission.

If you have questions about your privacy rights, please call the Providence Health & Services HIPAA Privacy Officer at (503) 574-9123.

**QUESTIONS:**
Any questions you have about this study can be answered by Dr. Brendan Curti at (503) 215-5696, Dr. Steven Seung at (503) 215-1819, or by Chris Fountain, RN at (503) 215-2691.

If you have any questions about your rights as a research subject, you may contact the Providence Health & Services Institutional Review Board at (503) 215-6560.

You may ask questions about this study at any time.

A description of this research study will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**CONSENT:**
I have read all of the above, asked questions and received satisfactory answers about what I did not understand. I agree to take part in this research study. I will be given a copy of this consent form.

Optional (not required) Biopsies
Please indicate if you agree, or not, to have two ultrasound-guided or CT-guided biopsies done on one of your tumors. Please indicate your choice by checking and initialing.

❑ I agree to have additional biopsies. Initials_____

❑ I **do not** agree additional biopsies. Initials_____

_____ _____
Date Patient Signature

_____
Print Patient Name

_____ _____
Date Person Obtaining Consent

## AUTHORIZATION FOR RELEASE AND DISCLOSURE OF MEDICAL INFORMATION

I agree to take part in this research study. As part of this study, authorized persons from Providence Health & Services Regional Cancer Program will need to collect information from other medical and health care providers to find out how effective and safe the study treatment was for me.

I authorize and direct all of my existing or future physicians and health care organizations who have my medical records including, but not limited to, private practice clinics, hospitals, nursing homes, and home health care agencies, to provide the Providence Health & Services Regional Cancer Program with copies of my medical records as they relate to this study.

In the event of my death, this consent will remain valid. If required by a legal or governing body, I authorize my personal representative or family member to fill out any additional forms necessary to confirm my consent for the release of my medical records/information.

Information obtained by the Providence Health & Services Regional Cancer Program will be used only in connection with this research study.

This consent to release medical records will stay in effect unless I change my mind. A copy of this release will be as valid as the original.

_____ _____

Date Patient Signature



PSJH IRB
IRB Number: PDX11-062
IRB Approval Date: 1/8/2021
IRB Parent Number: PDX11-062