***Remove the header information, remove or replace all instructional text and remove all inapplicable content from the document. For assistance with lay terminology, please see the Canadian Cancer Society Glossary of Terms at*** [***http://info.cancer.ca/e/glossary/glossary.html***](http://info.cancer.ca/e/glossary/glossary.html)

***The Provincial consent form should NOT be on local letterhead, nor include local contact information and should follow the OCREB template. Centres should keep the version date of the APPROVED Provincial consent form, and add their local contact information and all pre-approved, centre-specific, consent form changes***

Study Information and Informed Consent Form

*See Instruction Guide*

Study Title for Participants: *(Insert Lay Title here)*

Official Study Title for Internet Search on <http://www.ClinicalTrials.gov>: *(Insert Study Number “Insert Official Study Title”)*

Trial Code/study #: *(insert here)*

**Study Doctor:** Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 **Sponsor:** *(Sponsor name)*

*If an REB approved French consent is not used at your institution remove this statement.*

Le formulaire de consentement est disponible en français sur demande.

*A 24-7 phone number is required for studies that include greater than minimal risk research procedures or interventions*.

**EMERGENCY contact number** (24 hours/day 7 days/week): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Non-Emergency contact numbers are at the end of this document in the “Where can I get more information?” section.

When we say ‘you’ in this consent form, we mean you or your child; ‘we’ means the doctors and other staff.

*See Instruction Guide*

Overview and Key Information

1. What am I being asked to do?

We are inviting you to take part in a research study. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer. *(select from options 1a -1d)*

*Adapt one of the following text examples as appropriate for the study. Include type of cancer and, as applicable, relevant targeted mutations or treatment targets:*

*1a. Treatment or Imaging Study:* We are asking you to take part in this research study because you have advanced brain cancer.

*1b. Targeted Treatment Study:* We are asking you to take part in this research study because you have non-small cell lung cancer that has spread outside your lungs, and your cancer has a change in the gene called the EGFR (epidermal growth factor receptor) gene.

*1c. Prevention Study:* We are asking you to take part in this research study because you have a high risk of developing breast cancer.

*1d. Supportive Care Study:* We are asking you to take part in this research study because treatments for your cancer can cause side effects such as nausea and vomiting.

1. Taking part in this study is your choice.

You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It’s important that you have as much information as you need and that all your questions are answered. See the “Where can I get more information” section.

1. Why is this study being done?

*Adapt the following text for all studies with a simple question summarizing the study’s primary objective:*

This study is being done to answer the following question: *(Examples: Can the chance of your prostate cancer growing or spreading be lowered by adding a drug to the usual combination of drugs OR What are the side effects of a new drug and what is the right dose which could be used in future studies)*?

We are doing this study because we want to find out if this approach is better or worse than the standard of care for your *(select from options: 3a. type of cancer or precancerous condition; 3b. early detection; 3c. prevention of cancer; 3d. diagnosis; 3e. other)*. The standard of care is defined as care most people get for *(insert condition)*.

1. What is the standard of care for my *(select from options 3a – e above)*?

*See Instruction Guide*. *Adapt language from one of the following examples (4a – 4d) or use other language specific to your study. Provide a brief description of a standard of care.*

Standard of care

*4a. Examples for Treatment Studies:*

*4a.1:* The standard of care for patients who are not in a study is treatment with *(insert standard of care modality, e.g., more chemotherapy)*. *(Insert if appropriate: There are no treatments that are proven to help patients with your health condition live longer)*.

*4a.2:* The standard of care for patients who are not in a study is treatment with surgery, radiation, or drugs. Sometimes, combinations of these treatments are used. Your doctor can explain which treatment may be best for you. These treatments can reduce symptoms and may stop the tumour from growing for a few months or longer. *(Insert if appropriate: The standard of care is proven to help patients with your health condition live longer)*.

*4a.3:* The standard of care for patients who are not in a study is treatment with hormonal drugs. If the hormonal drugs stop working against your cancer, then doctors may use chemotherapy. For patients who get the standard of care for this cancer, about *(insert appropriate number)* out of 100 are free of cancer after 5 years.

*4b.4:* The standard of care for patients who are not in a study is treatment with surgery, chemotherapy, and radiation therapy. There are several chemotherapy drugs approved by Health Canada that are commonly used with the radiation therapy. For patients who get the standard of care for this cancer, about *(insert appropriate number)* out of 100 are free of cancer after 5 years.

*4b. Examples for Imaging Studies:*

*4b.1. for Diagnostic Imaging Studies:* The standard of care for patients who are not in a study is to take a picture of their tumour(s) with a *(insert as appropriate: CT, MRI, ultrasound, X-ray)*. This picture helps doctors diagnose your cancer. The *(insert as appropriate, e.g. CT, MRI, ultrasound, X-ray)* machine uses *(insert type of mechanism, e.g., radiation, magnets)* to take this picture.

*4b.2. Imaging Studies that Monitor Response to Treatment:* The standard of care for patients who are not in a study is to monitor the effect of treatment by taking pictures of their tumour(s) with a *(insert as appropriate, e.g. CT, MRI, ultrasound, X-ray)* machine over time. This means that you will get more than one *(insert as appropriate, e.g. CT, MRI, ultrasound, X-ray)* scan with a machine that uses *(insert type of mechanism, e.g., radiation, magnets)*.

*4c Supportive Care Studies:* The standard of care for patients who are not in a study is *(insert as appropriate, e.g. medication, etc.)*

*4d. Chemoprevention/ Studies:* The standard of care for patients who are not in a study to be followed closely by their doctor to watch for the development of cancer. Some patients may receive *(insert agent;*

*4e. Behavioral Studies:* The standard of care for patients who are not in a study is to get advice from their doctor. This advice might include ways to exercise and how to do their daily activities so they are less tired.

*Optional bullets should include, when appropriate, alternative procedures or interventions, watchful waiting, and/or palliative care.*

1. What are my choices if I decide not to take part in this study?
* You may choose to have the standard of care described above.
* You may choose to take part in a different research study, if one is available.
* *Consider adding as appropriate:* You may choose not to be treated for cancer.
* *Consider adding as appropriate:* You may choose to only get comfort care to help relieve your symptoms and not get treated for your cancer.

You may talk to your study doctor or usual doctor about the known benefits and risks of these other options before you decide about taking part in this study.

1. What will happen if I decide to take part in this study?

*See Instruction Guide. Adapt language from examples in 6a or 6b then adapt last paragraph to describe study follow-up.*

*6a. Non-Randomized Stud*y *or Phase 1 Study*: If you decide to take part in this study, you will get *(insert description of intervention, e.g., describe screening step, (e.g., to determine eligibility) study drugs or study approach)* for up to *(insert intervention length)*.

*6b. Randomized Study:* If you decide to take part in this study, you will either get *(insert description of intervention, e.g., describe screening step, (e.g., to determine eligibility) study drugs or study approach)* for up to *(insert intervention length)*, or you will get *(insert description of intervention, e.g., study drugs or study approach)* for up to *(insert intervention length)*.

After you finish *(insert description of intervention, e.g. your study treatment)*, your doctor will continue to follow your condition for *(insert study follow-up length)* and watch you for side effects *(or insert other purpose). (Include how the follow-up will occur, such as clinic visits or phone calls; how often, such as monthly, quarterly, annually; and how long the follow-up will continue).*

1. What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks

We want to make sure you know about a few key risks right now. You can find more information in section

13: “What risks can I expect from taking part in this study?”

If you choose to take part in this study, there is a risk that the *(study drug(s)/study approach)* may not be as good as *(the standard of care for your cancer / the other approach or study drug) at (shrinking or stabilizing your cancer / preventing your cancer from coming back / other explanation of benefit of other approach)*.

There is also a risk that you could have side effects from the *(study drug(s)/study approach)*. These side effects may be worse and may be different than you would get with the standard of care for *(you / your cancer)*.

***See Instruction Guide.***

Some of the most common side effects that the study doctors know about are:

* *(around 5 most important reasonably foreseeable risks and discomforts)*

There may be some risks that the study doctors do not yet know about.

Benefits

***See Instruction Guide.*** *Adapt language from one of the following examples (7a – 7e), then include last sentence about helping other people.*

*7a. Phase 0 Studies:* This study is not likely to help you. However, it may help the study doctors understand how this study drug works.

*7b. Phase 1 Studies:* There is some evidence (*select and modify as appropriate: in animals, in living human cells, in living animal cells, in people with another cancer)* that this treatment can *(shrink or stabilize)* cancer *(insert targeted mutation as appropriate, e.g. with a change in the EGFR gene)*, but we do not know if this will happen in people. It is unlikely that this *(insert intervention)* will help you live longer.

*7c. Phase 1 Studies:* There is some evidence *(select and modify as appropriate: in animals, in living human cells, in living animal cells, in people with another cancer)* that adding *(insert investigational drug)* to the standard of care can *(shrink or stabilize)* cancer for longer than the standard of care alone. However, we do not know if this will happen in people. It is unlikely that this *(insert intervention)* will help you live longer than the standard of care alone.

*7d. Phase 2 Non-randomized Studies:* This *(insert intervention)* has *(shrunk or stabilized)* your type of cancer *(select and adapt as appropriate: in a limited number of people with your cancer and in animals or in living human or living animal cells)*. It is unlikely that it will work in everyone with your cancer or help you live longer.

*7e. Phase 2 and 3 Randomized Studies:* There is evidence that this *(insert intervention)* is effective in *(shrinking or stabilizing)* your type of cancer. It is not possible to know now if the *(study drug(s)/study approach)* will *(extend your life / extend your time without disease / other primary endpoint)* compared to the standard of care.

This study may help the study doctors learn things that may help other people in the future.

1. If I decide to take part in this study, can I stop later?

You can decide to stop taking part in the study at any time. If you decide to stop, let your study doctor know as soon as possible. It’s important that you stop safely. *(Adapt and insert as applicable: This may mean slowly stopping the study drugs so that there is not a sudden unsafe change, risk to your health, etc.)*. If you stop, you can decide if you would like the study doctor to continue to contact you to find out how you are doing.

You may withdraw your permission to use your personal health information for this study at any time by letting the study doctor know. However, this would also mean that you withdraw from the study. Your study data that was recorded before you withdrew will be used but no information will be collected or sent to the sponsor after you withdraw your permission.

Your study doctor will tell you in a timely manner about new information or changes in the study that may affect your health or your willingness to continue in the study.

1. Are there other reasons why I might stop being in the study?

The study doctor may take you off the study if:

* Your health changes and the study is no longer in your best interest or you are unable to tolerate the study treatment.
* New information becomes available and the study is no longer in your best interest.
* You are unable to complete all required study procedures.
* *(Include as appropriate.)* For women: You become pregnant while on the study.
* *(Include as appropriate.)* If your treatment assignment becomes known.
* The study is stopped by Health Canada *(delete if not applicable*, the National Cancer Institute (NCI) *(delete if not applicable),* Research Ethics Board (REB), Food and Drug Administration (FDA) *(delete if not applicable)*, or study sponsor *(insert sponsor name in parentheses)*. The study sponsor is the organization who oversees the study.

---------------------------------------- End of Overview Section ----------------------------------

*Use the following text for all studies:*

**It is important that you understand the information in the Informed Consent Form before making your decision.** Please read, or have someone read to you, the rest of this document. If there is anything you don’t understand, be sure to ask your study doctor or nurse.

*See Instruction Guide.*

1. What is the purpose of this study?

*Adapt the following text examples, as applicable, or use other language specific to your study.*

***10a. Screening Step***

 *10a.1 Studies with a Screening Step (for Intervention or Study Pre-Registration) with Integral Biospecimens:* This study has a screening step. The purpose of this step is to test your tumour to find out if it has a specific *(gene change, mutation, or other evaluable change, e.g., protein, hormone, receptor, etc.)*. If it does and you meet all the study requirements, then we can assign you to treatment based on the results of the screening steps. *(Include following sentence if study will screen people out based on test results.)* If we find that your *(tumour or other specimen)* does not have the *(genetic changes or other results)* that are needed for this study, then your doctor will discuss other options for your care. *(If applicable, state if the screening result will assign them to a specific study drug/ treatment or study arm). (If applicable, state that this screening test is not approved by Health Canada for your disease)*.

*10b.2. Studies with a Screening Step (for Intervention or Study Pre-Registration) with Integral Imaging:* This study has a screening step. The purpose of this step is to find out if your cancer is in specific places in your body *(or insert other rationale)*. We will review *(insert type of imaging studies, e.g., CT scans, PET scans, etc.)* that you have already had. *(Include following sentence if study will screen people out based on test results.)* If your scans do not show the results needed for this study *(or specify what is needed for the study)*, your doctor will discuss other options for your care. *(If applicable, state if the screening scans help assign them to a study group*). *(If applicable, state that this screening test is not approved by Health Canada in your disease)*.

***10b. Treatment Studies***

*10b.1. Phase 1 Dose Escalation Studies:* The purpose of this study is to test the safety of a drug called *(insert name of study drug, e.g., TST1234)*. *(If applicable, include the following sentence.)* This drug has been tested in animals, but has not been tested in people. This study tests different doses of the drug to see which dose is safer for people. There will be about *(insert number)* people taking part in this study.

*10b.2. Phase 1 Novel Route/Combination Studies:* This study uses a combination of drugs *(insert names of drugs, e.g., carboplatin and paclitaxel)*. These drugs have already been approved to be given through a vein in your arm. The purpose of this study is to test if giving one of the drugs, *(insert name of drug, e.g., carboplatin)*, through a needle inserted into your belly at the same time that the other drug, *(insert name of study drug, e.g., paclitaxel)*, is given through the vein in your arm is safe. There will be about *(insert number)* people taking part in this study.

*10b.3. Phase 2 Non-randomized Studies:* The purpose of this study is to test the good and bad effects of the drug called *(insert name of study drug, e.g., bevacizumab)*. *(Insert name of study drug(s) or investigational approach)* could shrink your cancer, but it could also cause side effects, which are described in the risks section below. The study doctors hope to learn if the study drug will *(insert appropriate study endpoint, e.g., shrink the cancer by at least one quarter compared to its present size)*.

*The following sentence should be included only if the agent has not shown evidence of activity in humans.* We don’t know if *(insert name of study drug)* works to treat cancer in people, but it has shrunk several types of tumours in animals.

There will be about *(insert number)* people taking part in this study.

*10b.4. Phase 2 or 3 Randomized Studies:* The purpose of this study is to compare the standard of care alone to using *(specific study drug, surgery, or radiation approach)* plus the standard of care. The addition of *(insert name of study drug(s) or investigational approach)* to the standard of care could *(insert purpose, e.g. shrink your cancer or prevent it from returning)*. But, it could also cause side effects, which are described in the risks section below.

This study will help the study doctors find out if this different approach is *(adapt and insert as appropriate based on statistical design: better, the same, or worse)* than the standard of care. To decide if it is better, the study doctors will be looking to see if the *(study drug(s)/study approach)* increases the life of participants by 6 months or more compared to the standard of care *(edit or select other study primary endpoints as appropriate)*.

*The following two sentences should be included if appropriate and modified as necessary.* This chemotherapy drug, *(insert name of drug, e.g., docetaxel)*, is provided for use in *(insert type of cancer, e.g., prostate)* cancer. But, most of the time it is not used until *(e.g., hormone drug)* stops working. There will be about *(insert number)* people taking part in this study.

***10c. Imaging Studies****:*

*10c.1. Diagnostic, staging, response to therapy, or image-guided intervention*: The purpose of this study is to test *(insert name of study intervention, e.g., PET)* scans, which are a way to take pictures of your type of cancer. The study doctors want to see if *(insert name of intervention, e.g., PET, PET-CT, MRI, advanced MRI, ultrasound)* scans are *(adapt and insert as appropriate based on statistical design: better, the same, or worse)* than the *(insert as appropriate: scans or biopsy or surgery)* most often used to diagnose or monitor your cancer over time, *(insert name of standard of care, e.g., CT scans)*. If better, this *(insert name of intervention, e.g., PET)* scan should *(insert description of expected benefit)*. There will be about *(insert number)* people taking part in this study.

*10c.2. Phase 0/First-in-human Imaging Study:* The purpose of this study is to test if *(insert name of study intervention, e.g., F18-Fluoroglutamine)* can be used to take pictures of your type of cancer. This will be the first time that *(insert name of study intervention, e.g., F18-Fluoroglutamine)* is being tried in people. There will be about *(insert number)* people taking part in this study.

*10c.3. Phase 2 Non-randomized Imaging Agent Studies****:*** The purpose of this study is to test if an imaging drug called *(insert name of drug/agent, e.g., 18F-fluoride)* is useful for *(diagnosing or monitoring)* your type of cancer. The study doctors want to see if the *(insert type of scan, e.g., PET)* scan, used with the study drug, is better than the scans most often used to *(diagnose or monitor)* your type of cancer over time. There will be about *(insert number)* people taking part in this study

***10d. Supportive Care Studies:***

*10d.1. Chemotherapy Supportive Care Studies****:***You will be getting chemotherapy to treat your cancer. This treatment may cause nausea and vomiting. The purpose of this study is to test if *(insert name of drug/intervention)* can reduce your nausea and vomiting. The effects of *(insert name of drug/intervention)* will be compared to *(a placebo or the standard of care)*. *If applicable, include the following sentence.* A placebo is a *(insert appropriate description for the placebo, e.g., pill/liquid)* that looks like the study drug, but contains no medication. There will be about *(insert number)* people taking part in this study.

*10d.2. Pain Control Supportive Care Studies****:*** Your cancer may be causing pain. The purpose of this study is to test if *(insert name of drug/intervention)* can reduce your pain. The effects of *(insert name of drug/intervention)* will be compared to *(a placebo or the standard of care)*. *If applicable, include the following sentence.* A placebo is a *(insert appropriate description for the placebo, e.g., pill/liquid)* that looks like the study drug, but contains no medication. There will be about *(insert number)* people taking part in this study.

***10e Chemoprevention Studies:***

*10e.1. Phase 1 Dose Escalation Chemoprevention Studies****:***The purpose of this study is to test the safety of *(insert name of study drug or agent)* at different doses. “Dose” is defined as the amount of drug you get, *(insert potential dose amounts such as \_\_mg or \_\_mL)*. We want to find out what effects the drug has on people, if any. There will be about *(insert number)* people taking part in this study *(if desired insert participating countries: from Canada and insert other countries as applicable)*.

*10e.2. Phase 2 Non-randomized Chemoprevention Studies:* The purpose of this study is to test the safety of *(insert name of study drug or agent)* and find out what effect, if any, it has on people’s risk of developing *(insert type of cancer)* cancer. There will be about *(insert number)* people taking part in this study.

*10e.3. Randomized Chemoprevention Studies:* The purpose of this study is to compare the safety and effects of *(insert name of study drug or agent)* with the safety and effects of *(insert name of currently-used drug or placebo)* on people’s risk of developing *(insert type of cancer)* cancer. In this study, you will get either *(insert name of study drug or agent)* or a placebo. A placebo looks like the study drug, but contains no medication. You will not know if you are getting the study drug or placebo. There will be about *(insert number)* people taking part in this study.

***10f. Behavioral Studies:***

You will be getting chemotherapy to treat your *(insert type of cancer)* cancer. This treatment may cause tiredness. The purpose of this study is to test if *(insert intervention, e.g., yoga)* can reduce your tiredness. The effects of *(insert intervention)* will be compared to *(describe comparative intervention, e.g., listening to relaxation tapes, or the standard of care)*.

***See Instruction Guide.***

***10g. Studies with Investigational Integral Biomarker(s)***

*(Insert as appropriate: Another purpose of this study)* is for the study doctors to learn if a *(insert name of biomarker being tested for)* test is helpful to decide *(insert purpose of biomarker test, e.g., which study group you will be in)*. An *(insert how biomarker sample will be obtained, e.g., extra tube of blood will be drawn or tissue from your surgery will be used)* for the test. The study doctors do not know if using the test is *(adapt and insert as appropriate based on statistical design: better, the same, or worse)* than not using the test. If better, this test should *(insert description of expected benefit)*. There will be about *(insert number)* people taking part in this study.

1. What are the study groups?

***See Instruction Guide.*** *Adapt one of the following text examples 11a -11b*

***11a Treatment Studies***

*11a.1. Phase 1 Dose Escalation Studies:* Different people taking part in this study will get different doses of the study drug *(insert name of study drug)*. *(Insert appropriate description of treatment schedule, including route of administration, e.g. as a pill you take by mouth, through a vein in the arm, or other route; and schedule.*) Treatment schedule: You will get *(insert name of study drug)* through a vein in your arm on the first and eighth day of each cycle. Each cycle lasts *(21)* days. This study has *(4)* cycles. *(Include the following sentence if you are including a study calendar.)* See the study calendar for more information.

The first *(insert number)* people taking part in this study will get the lowest dose. If the drug does not cause serious side effects, the next group of people in the study will get a higher dose. The study doctor will watch each group carefully as they increase the dose. The doses will continue to increase for every new group until people have serious side effects that require the dose to be lower. Once this dose is found, the study is stopped.

*11a.2. Phase 1 Dose Escalation and Dose Expansion Studies:* There are two parts in this study, a dose escalation part and a dose expansion part. Your doctor will tell you which part you are in.

In the dose escalation part of this study, different people will get different doses of the study drug *(insert name of study drug). (Insert treatment schedule here if different from treatment schedule used in dose expansion – see example below).*

The first *(input number)* people taking part in this study will get the lowest dose. If the drug does not cause serious side effects, the next group of people in the study will get a higher dose. The study doctor will watch each group carefully as they increase the dose. The doses will continue to increase for every new group until people have serious side effects that require the dose to be lower. Once this dose is found, the dose escalation is stopped.

In the dose expansion part of this study, the highest dose with manageable side effects will be given to *(insert number)* more people. This will help study doctors better understand the side effects that may happen with this drug.

*(Insert appropriate description of treatment schedule, including route of administration, e.g. as a pill you take by mouth, through a vein in the arm, or other route; and schedule.)* Treatment schedule: You will get *(insert name of study drug)* through a vein in your arm on the first and eighth day of each cycle. Each cycle lasts *(21)* days. This study has *(4)* cycles. *(Include the following sentence if you are including a study calendar.)* See the study calendar for more information.

*(Include and adapt the following sentences as applicable)* You *(insert appropriate information, e.g., will/will not)* be able to get additional doses of the drug.

*11a.3: Phase 2 Non-randomized Studies*

In this study, you will get the usual radiation therapy and chemotherapy *(insert usual chemotherapeutics, e.g., 5-fluorouracil or capecitabine)*. You also will get the study drug *(insert name of study drug)*.

*(Insert appropriate description of treatment schedule, including any radiation therapy or surgery, and for drugs include route of administration, e.g. as a pill you take by mouth, through a vein in the arm, or other route; and schedule.)* Treatment schedule: You will get *(insert name of study drug)* through a vein in your arm on the first and eighth day of each cycle. Each cycle lasts *(21)* days. This study has *(4)* cycles. *(Include the following sentence if you are including a study calendar.)* See the study calendar for more information.

*(Include and adapt the following sentences as applicable.)* You *(insert appropriate information, e.g., will/will not)* be able to get additional doses of the drug.

*11a.4: Phase 2 Novel Route of Administration Study*

This study has 2 study groups.

* **Group 1**If you are in this group, you will get *(insert name of drug, route of administration [as a pill you take by mouth, through a vein in the arm, or other route], and schedule. For example, “You will get [name of drug] as a pill you take by mouth two times a day for [number of days] days.”)* *(Include the following sentence if you are including a study calendar.)* See the study calendar for more information.

*(Include the following sentence as applicable.)* You also will keep a pill diary. This helps you keep track of when you take your pills. The study doctor will show you how to use this diary. Each time you visit the clinic, you must bring the pill diary, any remaining pills, and the pill bottle.

There will be about *(insert number)* people in this group.

* **Group 2**If you are in this group, you will get *(insert name of drug, route of administration [as a pill you take by mouth, through a vein in the arm, or other route], and schedule. For example, “You will get [name of drug] through a vein in the arm on the first and eighth day of each cycle. Each cycle lasts 21 days. This study has 4 cycles”.)* *(Include the following sentence if you are including a study calendar.)* See the study calendar for more information.There will be about *(insert number)* people in this group.

*11a.5: Randomized Phase 2 Blinded, Placebo-Controlled Treatment Studies*

This study has 2 study groups. You will not be told which group you are in.

* **Group 1**If you are in this group, you will get the usual drug used to treat this type of cancer, *(insert name of usual drug)*, plus a study drug called *(insert name of drug, e.g., docetaxel)*. You will get these drugs *(insert route of administration [as pills you take by mouth, through a vein in the arm, or other route] and schedule, for example: “as pills you take by mouth two times a day for [number of days] days.)* *(Include the following sentence if you are including a study calendar.)* See the study calendar for more information.

*(Include and adapt the following sentences as applicable.)* You *(insert appropriate information, e.g., will/will not)* be able to get additional doses of the drug.

There will be about *(insert number)* people in this group.

* **Group 2**If you are in this group, you will get the usual drug used to treat this type of cancer, *(\*insert name of drug[s]\*)*, plus a placebo. A placebo *(\*insert appropriate description for the placebo, e.g., is a pill/liquid that\*)* looks like the study drug, but contains no medication.

You will get the drug and placebo *(insert route of administration [as pills you take by mouth, through a vein in the arm, or other route] and schedule, e.g. as pills you take by mouth two times a day for [number of days] days)*. *(Include the following sentence if you are including a study calendar.)* See the study calendar for more information.

There will be about *(insert number)* people in this group.

*11a.6: Phase 3 Randomized Studies*

This study has 2 study groups. You will not be told which group you are in.

* **Group 1**

If you are in this group, you will get the usual drug used to treat this type of cancer *(insert name of drug)*. You will get this drug *(insert route of administration [as a pill you take by mouth, through a vein in the arm, or other route] and schedule, e.g. through a vein in the arm on the first and eighth day of each cycle. Each cycle lasts 21 days. This study has 4 cycles)*. *(Include the following sentence if you are including a study calendar.)* See the study calendar for more information.

There will be about *(insert number)* people in this group.

* **Group 2**

If you are in this group, you will get a study drug called *(insert drug name, e.g., docetaxel)* plus the usual drug used to treat this type of cancer, *(insert name of drug)*. You will get these drugs *(insert route of administration [as a pill you take by mouth, through a vein in the arm, or other route] and schedule, e.g. through a vein in the arm on the first and eighth day of each cycle. Each cycle lasts 21 days. This study has 4 cycles)*. *(Include the following sentence if you are including a study calendar.)* See the study calendar for more information.

*(Include and adapt the following sentences as applicable.)* You *(insert appropriate information, e.g., will/will not)* be able to get additional doses of the drug.

There will be about *(insert number)* people in this group.

*Use the following text, adapted and including an appropriate probability, as applicable.*

We will use a computer to assign you to one of the study groups. This process is called “randomization.” It means that your doctor will not choose and you cannot choose which study group you are in. You will be put into a group by chance. You will have *(insert appropriate probability, e.g. an equal)* chance of being in Group 1 or Group 2 *(or insert appropriate description of assignments).*

***11b. Chemoprevention Studies***

*11b.1. Phase 1 Dose Escalation Chemoprevention Studies:* Different people taking part in this study will get different doses of the study drug *(insert name of study drug). (Insert treatment schedule as appropriate – see text examples in other examples.)*

Different doses of the study drug *(insert name of research drug)* will be given to some study participants. The first *(input number)* people taking part in this study will get the lowest dose. If the drug does not cause serious side effects, the next group of people in the study will get a higher dose. The study doctor will watch each group carefully as they increase the dose. The doses will continue to increase for every new group until people have serious side effects that require the dose to be lower. Once this dose is found, the dose escalation is stopped. Then the study is stopped.

*11b.2: Randomized Phase 2 Chemoprevention Studies:* This study has two study groups. Group 1 will receive the study drug *(insert name of research drug)* and Group 2 will receive a placebo. A placebo *(insert appropriate description for the placebo, e.g., pill/liquid)* looks like the study drug, but contains no medication. *(Insert treatment schedule as appropriate – see text examples in other examples)*.

(Include and adapt the following sentences as applicable.) You *(insert appropriate information, e.g., will/will not)* be able to get additional doses of the drug.

*Use and adapt the following text when including a study schema. Use of a simple study schema is strongly encouraged regardless of study design.*

Another way to find out what will happen to you during this study is to read the chart below. Start reading *(if using a horizontal schema: at the left side and read across to the right. If using a vertical schema: from the top and read to the bottom)*, following the lines and arrows.

*Schema Example: Simple Randomization*

Randomize –

The computer will randomly put you in a study group.

**Group 2**

Hormone therapy + Chemotherapy

(Study group)

You agree to take part in the study and sign this consent form.

**Group 1**

Hormone therapy

(Usual approach group)

***See Instruction Guide.***

1. What exams, tests, and procedures are involved in this study?

Before you begin the study, your doctor will review the results of your exams, tests, and procedures. This helps your doctor decide if it is safe for you to take part in the study. If you join the study, you will have more exams, tests, and procedures to closely monitor your safety and health. Most of these are included in the standard of care you would get even if you were not in a study although some tests may be done more frequently, if required.

*Use the next paragraph if the study requires tests outside of the standard of care to monitor the effects of the study agent or prevent complications.* Listed below are exams, tests, and procedures that need to be done as part of this study to monitor your safety and health, but may not be included in the standard of care. We will use them to carefully follow the effects of the study treatment, including preventing and managing side effects

*Only use the next paragraph if the study requires tests outside of the standard of care to monitor the effects of the study agent or prevent complications. Edit the text to include tests as appropriate for the study. The tests should be listed with the timing when they occur in the study.*

These exams, tests, and procedures to monitor your safety and health include:

* *(An eye exam before you begin the study.*
* *Blood counts done weekly during the first cycle of treatment.*
* *Blood test before you begin the study to determine HIV/hepatitis status.*
* *Magnetic resonance imaging (MRI) done every 6 weeks – a scan that uses a strong magnet to produce pictures of areas inside the body such as organs and other tissue, and inside of bones.*

 *If applicable MRI scans often involve injecting a dye into your vein.*

* *Computed tomography (CT) scan done every 6 weeks – 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.*
* *If you are of childbearing potential, a pregnancy test will be done before each cycle.*
* *A special test to study your heart (either a MUGA scan or an echocardiogram (ECHO) will be done before each cycle.*
* *Positron emission tomography (PET) done every 12 weeks – a scan to help show how organs and tissues are working by tracing where a small amount of glucose (a sugar) that includes a tiny, harmless amount of radioactivity, goes in your body after it has been injected into one of your veins.*
* *An x-ray of your bones (skeletal survey) every 6 months.*
* *An electrocardiogram (EKG), that checks how your heart is functioning by measuring the electrical activity of the heart, will be done every other cycle.*
* *Thyroid testing done every other cycle.*
* *Physical exams done weekly during the first cycle).*

*If applicable: i.e., for centres for which satellite sites are being used and/or for centres for which certain tests or procedures (e.g., scans) may take place at another location. Centre-specific: only use and adapt the next paragraph if the following will be required.*

Some study-specific (*treatments/procedures/tests/activities)* for this study may take place *closer to your home or at another location*. The information from these (*treatment/procedures/tests)* will be sent to your study doctor. Your study doctor will discuss this information with you, if this is a possibility.

*Only use and adapt the next 2 paragraphs if the study involves return of incidental genetic test results.*

**Genetic Testing**

This study will use genetic tests that may identify changes in the genes in your *(insert either DNA / tumour DNA / other appropriate description)*. Your genes carry information about you and your family, from the color of your eyes to health conditions for which you may be at risk, such as certain kinds of cancer.

Finding these changes would not affect your treatment in this study. However, they could affect your health in other ways. *(Insert plan for return of results, such as: If these changes are identified, your study doctor will be notified of the result. You will be given the opportunity to decide whether you wish to be made aware of this information on the last page of this consent form. You may change your decision at any time by letting your study doctor know. Example: If you decide to be made aware of this information, your study doctor will explain the process. This may include additional testing to confirm the results, and genetic counselling to help you understand what this result could mean for you or your blood relatives, such as your siblings and/or children..)*

***See Instruction Guide.***

**Tissue/Blood/Urine Collection (Required)**

*Adapt as many of the following text examples, as applicable, or use other language specific to your study.*

*12a. Mandatory Specimen Collection Needed for Research Purposes Only.*

You will need to have *(a biopsy / a blood sample taken)* for the study. *(Insert information about when the sample will be taken, for example, before you begin study drug; after the third dose; etc.)*. The study biopsy takes small pieces of cancer tissue from your body. This is like the biopsy you had that helped diagnose your cancer. *(Include a brief description of how the specimen will be used for research purposes. For example, The purpose of this sample collection is to make sure you have the type of cancer that is being studied and/or to see how the cancer responds to the study treatment)*. You *(and/or)* your study doctor *(will/will not)* get the results of this testing. If you agree to take part in the study, signing this consent form means that you are consenting to the collection of your tissue sample together with any related health information from the hospital or clinic where it was collected.

These samples will be sent to a laboratory at the (*state Institution, City, Country note: minimum required location is Country. The retention period is).*If you no longer want your samples to be used in this research, you should tell your study doctor. Your study doctor will notify the sponsor who will ensure the samples are returned to the hospital from which they were obtained if needed, or destroyed. If tests have already been done on your sample(s) it will not be possible to withdraw those results. However, no further testing will be done.

If you are a First Nations or an indigenous person who has contact with Elders, you may want to talk to them before you make a decision about this research study. Elders may have concerns about some research procedures including genetic testing.

*12b. Use of Existing Tissue Specimen*

Your study doctor will need to use some of the tissue left over from your surgery or biopsy when you were diagnosed with cancer. This sample is a required part of the study. *(Include a brief description of how the specimen will be used for research purposes.*  *For example, The purpose of this sample collection is to make sure you have the type of cancer that is being studied and/or to see how the cancer responds to the study treatment)*. You *(and/or)* your study doctor *(will/will not)* get the results of this testing.

If you agree to take part in the study, signing this consent form means that you are consenting to the collection of your tissue sample together with any related health information from the hospital or clinic where it was collected.

These samples will be sent to a laboratory at the (*state Institution, City, Country note: minimum required location is Country. The retention period is).*If you no longer want your samples to be used in this research, you should tell your study doctor. Your study doctor will notify the sponsor who will ensure the samples are returned to the hospital from which they were obtained if needed, or destroyed. If tests have already been done on your sample(s) it will not be possible to withdraw those results. However, no further testing will be done.

If you are a First Nations or an indigenous person who has contact with Elders, you may want to talk to them before you make a decision about this research study. Elders may have concerns about some research procedures including genetic testing.

*12c. Use of Existing Tissue Specimen if Available or a New Specimen Collection if Necessary*

Your study doctor will need to use some of the tissue left over from your biopsy when you were diagnosed with cancer. This sample is a required part of the study. *(Include a brief description of how the specimen will be used for research purposes*. *For example, The purpose of this sample collection is to make sure you have the type of cancer that is being studied and/or to see how the cancer responds to the study treatment)*. You *(and/or)* your study doctor *(will/will not)* get the results of this testing.

If there is not enough tissue left over from your biopsy, your study doctor will need to do another biopsy to get this tissue. *(Insert information about when the sample will be taken, for example, before you begin study drug; after the third dose; etc.)*. The study biopsy takes small pieces of cancer tissue from your body. This is like the biopsy you had that helped diagnose your cancer. *(Include a brief description of how the specimen will be used for research purposes)*. You *(and/or)* your study doctor *(will/will not)* get the results of this testing. If you agree to take part in the study, you may need to sign a separate consent form for the study biopsy at the hospital or clinic where the biopsy is done.

If you agree to take part in the study, signing this consent form means that you are consenting to the collection of your tissue sample together with any related health information from the hospital or clinic where it was collected.

These samples will be sent to a laboratory at the (*state Institution, City, Country note: minimum required location is Country. The retention period is).* If you no longer want your samples to be used in this research, you should tell your study doctor. Your study doctor will notify the sponsor who will ensure the samples are returned to the hospital from which they were obtained if needed, or destroyed. If tests have already been done on your sample(s) it will not be possible to withdraw those results. However, no further testing will be done.

If you are a First Nations or an indigenous person who has contact with Elders, you may want to talk to them before you make a decision about this research study. Elders may have concerns about some research procedures including genetic testing.

*12d. Mandatory Quality of Life or Participant-Reported Outcomes Assessments*

**Questionnaires**

If you choose to take part in this study, you will be asked to fill out a form with questions about *(briefly state topic, e.g., your physical and emotional well-being)*. Researchers will use this information to *(briefly describe purpose, e.g., learn more about how cancer and cancer treatment affects people)*.

*(Include and adapt the following two sentences as appropriate.)* Since these forms are being used for research, the responses you provide will not be shared with your study doctor. If you have any serious health issues or other concerns, please talk with your doctor or nurse right away.

You will be asked to fill out this form at *(insert number)* times:

* *(insert bulleted list of time indicators, e.g., before surgery, after surgery before chemotherapy, and mode, e.g., inpatient, mail, or phone)*.

Each form will take about *(insert number)* minutes to complete. The forms will ask about things like *(briefly describe, e.g., tiredness, diarrhea).* You don’t have to answer any question that makes you feel uncomfortable.

***See Instruction Guide.***

**Study Calendar**

*12e. Optional Study Calendar****:*** *Use and adapt the following statement if a participant study calendar is included in the consent or as an attachment to the ICF*.

See the participant study calendar *below or*  attached at the end of this document. It shows how often the study *(insert appropriate words, e.g., exams, tests, and/or procedures)* will be done.

***See Instruction Guide.***

1. What risks can I expect from taking part in this study?

The risks and side-effects of the standard procedures will be explained to you as part of your standard of care and therefore are not listed.

*Adapt the following text to accurately describe the general risk that the study drug/study approach/study intervention may not be effective:*

General Risks

If you choose to take part in this study, there is a risk that the *(study drug(s)/study approach)* may not be as good as *(the standard of care for your cancer or condition / the other approach or study drug)* at *(shrinking or stabilizing your cancer / preventing your cancer from coming back)*.

*From the following text, select reasonably foreseeable risks and discomforts and/or add others. Note that physical side effects are described later and should not be duplicated.*

You also may have the following discomforts:

* Spend more time in the hospital or doctor’s office.
* Be asked sensitive or private questions about things you normally do not discuss.
* May not be able to take part in future studies.

*Use and adapt the following text for all studies as required by the protocol, and include additional detail as required.*

The *(specify intervention)* used in this study could be very harmful to an unborn or newborn baby. There may be some risks that doctors do not yet know about. It is very important that you check with your study doctor about methods to prevent pregnancy to use during the study and for *(insert time in months/years)* after you have completed the study (*or the last dose)*. Some of the drugs used in this study may make you unable to have children in the future. Your study doctor will discuss this with you.

Any results of pregnancy testing will be provided to the participant only and not to the guardian/parent.

*Use and adapt the following text for protocols involving mandatory submission of tissue samples that may be depleted.*

This study will use a sample of your tissue.  Generally, your hospital will keep some of your tissue.  This tissue may be used to help treat your cancer in the future.  Because this study will need to use some of this tissue, there is a small risk that it could be used up.  Please speak to your study doctor to discuss this risk.

***See Instruction Guide****.*

*13a. If applicable, adapt the following text examples for risks of genetic or non-genetic testing*

Genetic Testing Risks

*Use this section if applicable. Carefully revise, add, and tailor the text examples for studies using investigational testing to best describe the specifics of the study. Language and subheading should also be adapted for non-genetic investigational testing used for the purposes of study eligibility or group assignment.*

*13a.1. Studies Using Investigational Genetic Test Results to Determine Study Eligibility and Assign Participants to Study Groups*

As part of this study, we are also studying a genetic test. The test is designed to find out if your tumour has the genetic changes that are needed for this study. If it does, we will assign you to a study group based on the genetic changes in your tumour.

Because this genetic test is still being studied, there is a risk that the test results may be wrong. If the test results are wrong, you may be included in this study even though it may not offer the best treatment option for you. Or, you may not be included in this study even though it may offer a good treatment option for you.

*13a.2. Studies Using Genetic Testing of Tumour Tissue Alone to Identify Potentially Inheritable Mutations*

The genetic test used in this study will test your tumour for *(a genetic change or genetic changes), (specify which changes, e.g., BRCA1)*. This change also may be in your normal tissue and passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down.

Since this study is only testing tumour tissue, we will not know if a genetic change in your tumour is also in your normal tissue. If you want to find out if the change is in your normal tissue, then you will need to get other tests done outside of this study.

Genetic tests of normal tissue can reveal information about you and also about your relatives. Your study doctor will talk with you about what testing your normal tissue may mean for you and your family. He or she also may suggest that you talk with a genetics counselor to learn more.

*13a.3. Studies Using Genetic Testing of Tumor Tissue and Normal Tissue to Identify Inheritable Mutations*

The genetic test used in this study will test your tumor and normal tissue for *(a genetic change or genetic changes), (specify which changes, e.g., BRCA1)*. Changes found in your normal tissue may be passed down in families. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down.

Genetic tests of normal tissue can reveal information about you and also about your relatives. Your doctor will talk with you about what the tests results may mean for you and your family. He or she also may suggest you talk with a genetics counselor to learn more. You or your insurance plan would have to pay for visits to a genetic counselor.

*If applicable, include risks of research biopsy or other research specimen collection.*

Biopsy Risks

Common side effects of a biopsy are a small amount of bleeding at the time of the procedure, bruising, and pain at the biopsy site. Pain can be treated with regular pain medications. Rarely, an infection can occur. You may sign a separate consent form for the study biopsy that describes the risks in more detail.

*If there is any leftover specimen that may possibly be stored for biobanking, indicate here that this will be discussed in the section under “Optional studies”.*

*Use and adapt the following required text describing research side effects for all studies.*

Side Effect Risks

The *(specify type(s) of study intervention, such as surgery, radiation therapy, drugs, etc.)* used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will test your blood and let you know if changes occur that may affect your health.

There is also a risk that you could have other side effects from the study *(specify type(s) of study intervention, such as surgery, radiation therapy, drugs, etc.).*

*If applicable:*

Long term effects of the *specify - radiation therapy / chemotherapy / radiation from imaging tests* used in this study include an increased risk of developing other cancers.

Here are important things to know about side effects:

1. The study doctors do not know who will or will not have side effects.
2. Some side effects may go away soon, some may last a long time, and some may never go away.
3. *(Include as appropriate for study and population.)* Some side effects may make it hard for you to have children.
4. Some side effects may be mild. Other side effects may be very serious and even result in death.

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

* If you notice or feel anything different, tell your study doctor. He or she can check to see if it is a side effect.
* Your study doctor will work with you to treat your side effects.
* Your study doctor may adjust the study drugs to try to reduce side effects.

*(Include the following two sentences for studies looking at a new combination of drugs and modify if additional details about the interaction are known.)* This study is looking at a combination of the usual drugs used to treat this type of cancer plus a study drug. This different combination of drugs may increase your side effects or may cause new side effects.

*See Instruction Guide*

*13b. Use the following required text and adapt the risk lists as applicable*

Drug Risks

The lists below show the most common and most serious side effects doctors know about. Keep in mind that there might be other side effects doctors do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

*If applicable, adapt the following to provide risk information.*

**Possible Side Effects of *(Study Agent)***

**COMMON, SOME MAY BE SERIOUS**In 100 people receiving *(study agent name)*, more than 20 and up to 100 may have:

* Risk

**OCCASIONAL, SOME MAY BE SERIOUS**In 100 people receiving *(study agent name)*, from 4 to 20 may have:

* Risk

**RARE, AND SERIOUS**In 100 people receiving *(study agent name)*, 3 or fewer may have:

* Risk

*When limited numbers of individuals have been exposed to the drug (fewer than 100), and the risks cannot accurately be quantified, one of the following phrases should be included (if applicable):*

As of *date,* only *X* people have been given this drug and the side effects that have been reported are:

* *X* experienced *headaches*
* *X* experienced *diarrhea*

It is not yet known if these side effects are caused by *agent* or how likely these side effects will be.

*Or if applicable:*

The study drug *agent* is in an early phase of development and so the side-effects in humans are unknown at this time. Animal studies to date show *list as per Investigator Brochure using lay language*.

*Use the following text if drug interaction risks are expected.*

Additional Drug Risks

The study drug could interact with other drugs *(include if appropriate: and food). (Insert description of the potential interactions)*. *(Include the following two sentences if appropriate)*. Your study doctor will give you a drug information handout that lists these possible interactions. Share this information with your family members, caregivers, other health care providers, and pharmacists.

*Use the following text for all drug studies.*

Rarely, there are problems getting enough supplies of the study drug. If that happens, your doctor will talk with you about your options.

*If applicable:*

Some cancer treatments such as chemotherapy or other drugs may slightly increase the risk of blood clots in your veins. Please tell your study doctor if you have any new swelling in a leg or arm or have a sudden problem with your breathing. These may be signs of a clot forming or a clot moving to your lungs. Clots can be treated with blood thinners. If you experience any of these symptoms you should go to the nearest medical clinic or hospital and contact your study doctor as soon as possible.

*If applicable, adapt the following text and table examples to describe study risks and side effects of imaging studies. These risks should also be included if there is additional imaging that is not standard of care to describe the extra research risks involved. .*

Imaging Risks

*Text Example of Radiation Risk for Research Imaging Studies*

The *(insert type of scan, e.g., PET, CT)* that you get in this study will expose you to low amounts of radiation. Every day, people are exposed to low levels of radiation that come from the sun and the environment around them. This type of radiation is called “background radiation.” No one knows for sure whether exposure to these low amounts of radiation is harmful to your body.

The *(insert type of scan, e.g., PET, CT)* that you get in this study will expose you to more radiation than you get from everyday background radiation. The amount of radiation from this scan is the same as *(insert estimate, e.g., 2 years’ worth)* of background radiation. Most of the time, this amount of extra radiation is not harmful to you. However, scientists believe that being exposed to too much radiation can cause harmful side effects. This could include getting a new cancer. We estimate that this could happen in about 1 out of every 1000 people who get a very large amount of extra radiation.

*Example x, use if applicable: Allergy Risk for Research Imaging Studies*

As part of the *(insert type of scan, e.g., PET, CT)* that you get in this study, iodine or another imaging agent will be injected into your vein. Some people are allergic to the imaging agent. Let your study doctor know if you have an allergy to iodine or to other imaging agents or seafood or if you have kidney problems.

*Example x, use if applicable: Breast Imaging Studies*

If you are in the digital mammogram group, every time you have a mammogram in this study, the amount of radiation that you will receive is the same amount that you ordinarily receive from the environment over about one month of your life. If you are in the tomosynthesis mammogram group, every time you have a mammogram in this study, the amount of radiation you will receive is doubled compared to digital mammography – that is the same radiation dose you would ordinarily receive from the environment over about two months of your life. Regardless which group you are in, the dose that you receive may vary a bit. A woman who has larger or more dense breasts will receive more radiation than a woman with smaller or less dense breasts.

*If applicable, adapt the following text and table examples to describe study risks and side effects of radiation therapy studies. Examples should be modified to add possible side effects related to treatment location.*

**Possible Side Effects of Radiation Therapy**

**COMMON, SOME MAY BE SERIOUS**In 100 people receiving radiation therapy, more than 20 and up to 100 may have:

* Risk

**OCCASIONAL, SOME MAY BE SERIOUS**In 100 people receiving radiation therapy, from 4 to 20 may have:

* Risk

**RARE, AND SERIOUS**In 100 people receiving radiation therapy, 3 or fewer may have:

* Risk

***See Instruction Guide.***

1. **What are my responsibilities in this study?**

If you choose to take part in this study you will need to:

* Keep your study appointments.
* *For studies using non-marketed drugs or other investigational interventions, include as appropriate:* Make every effort to return to the clinic/hospital where the study drug was given if you experience serious side effects that require treatment.
* Tell your study doctor about:
	+ all medications (prescription and non-prescription) and supplements you are taking, including vitamins and herbals, and check with your study doctor before starting, stopping, or changing any of these. This is for your safety as these may interact with the treatment you receive on this study.
	+ any side effects
	+ any doctors’ visits or hospital stays outside of this study
	+ if you have been or are currently in another research study, or are thinking about participating in another study
* *(Include as appropriate)* Return any unused study medication, and completed diaries and questionnaires
* *(Include as appropriate)* Write down in your medication diary when you take the study drug at home.
* *(Include as appropriate)* Avoid eating/drinking *(specify what/for how long)*

*Use and adapt the following text for all studies as required by the protocol, and include additional detail as required.*

**For women:** Do not get pregnant or breastfeed while taking part in this study. **For men:** Do not father a baby while taking part in this study. **For all:** Tell your study doctor right away if you think that you or your partner have become pregnant during the study or within *(insert time in months/years)* after your last dose of study drug *(or modify for study treatment)*. Your study doctor will let the sponsor know about the pregnancy. If you become pregnant, your study doctor will gather information on the outcome of the pregnancy from your medical/study record and will provide it to the sponsor.

**15. What are the costs of taking part in this study?**

***See Instruction Guide.*** *Include and adapt the following text if one or more study agent is provided free to participants. Clearly state if study agent is covered for one group of participants but not others.*

You will not have to pay for the *(insert name of study agent(s))* while you take part in this study and the study is ongoing. The costs of your standard of care medical treatment will be paid for by your provincial medical plan to the extent that such coverage is available. There may be extra costs that are not covered by your medical plan that you will have to pay yourself, some examples may be physiotherapy or certain pain medications.

*Use the following text if the study may require more frequent clinic visits than the standard of care.*

Taking part in this study may mean that you need to make more visits to the clinic or hospital than if you were getting the standard of care to treat your cancer. You may:

* Have more travel costs.
* Need to take more time off work.
* Have other additional personal costs.

*Use the following text for all studies*

You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

*If appropriate, insert a description of any compensation for participation or reimbursement for expenses.*

You will be reimbursed for study-related expenses such as [specify, e.g., parking]

*If return of genetic testing results is planned, add language regarding cost as applicable:*

If you choose to be told about genetic testing results that are found during participation in this study, results will need to be confirmed in a laboratory that is not associated with the research study. These services may not be covered by your provincial health care plan and may only be available if you or your private insurance pay for them.

16. What happens if I am injured because I took part in this study?

*Use the following text for all studies*

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. In case of research injury or side effects, medical care will be provided or you will be referred for appropriate medical care at no cost to you.

By signing this form you do not give up any of your legal rights against the investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

***See Instruction Guide.***

1. Who will see my medical information?

Your privacy is very important to us. Every effort will be made to protect it. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

Some of your health information, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. However, information that is put in the database will contain only coded information If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

There are organizations and their representatives that may look at or receive copies of some of the information in your study records for data analysis and quality assurance. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group. Some of these organizations are: *(Modify the following text as necessary for all studies.)*

* The study sponsor *[insert name*] and any company supporting the study *(or the study agent/treatment)* now or in the future. This would include any organization helping the sponsor with the study. *Delete company reference if not applicable.*
* The *Ontario Cancer* Research Ethics Board (REB), which is a group of people who review the research with the goal of protecting the people who take part in the study.
* Health Canada because they oversee the use of drugs in Canada and similar regulatory authorities such as the European Medicine Agency because they oversee the use of drugs in other countries.
* U.S. Food and Drug Administration (FDA) because they oversee the use of drugs in other countries. *(Remove this bullet for studies where the FDA will not see study data.)*
* The NCI and the groups it works with to review research. *(Remove this bullet for studies that are not NCI affiliated.)*
* *(For NCTN trials, add the following language.)* The NCI’s National Clinical Trials Network and the groups it works with to conduct research *(insert if appropriate: including the Imaging and Radiation Oncology Core (IROC))*.
* *(Any other relevant trial organizations should be listed here.)*

*Choose one of the following: Note: All NCI studies must use the #1 statement*

*1.* In addition to storing data in the study database, data from studies that are publicly funded may also be shared for future use in public databases with protections for your privacy. The goal of this data sharing is to make more research possible which may improve people’s health. Your study records may be stored and shared for future use in public databases. However, your name and other personal information will not be used*.*

*2.*Your study records may be stored and shared for future use. However, your name and other personal information will not be used*.*

*For all studies. Modify the third point as needed.*

Some types of future research may include looking at your information and information from other participants to see who had side effects across many studies or comparing new study data with other study data. However, right now we don’t know what research may be done in the future using your information. This means that:

1. You will not be asked if you agree to take part in the specific future research studies using your health information.
2. You and your study doctor will not be told when or what type of research will be done.
3. *(if )* You will not get reports or other information about any research that is done using your information.

*Use the following required text when mandatory samples are collected as part of the study.*

To protect your identity, the information that will be on your samples will be limited to coded information.

*Use the following required text when conducting genetic testing as part of the study.*

There is a risk that someone could get access to your genetic information and identify you by name. The study doctors believe the risk of this happening is very small. However, the risk may increase in the future as people find new ways of tracing information. For more information about how your genetic information is protected ask your study doctor.

1. **Conflict of Interest**

This centre is receiving funds from *(insert source)* to help offset the costs of conducting this research. ***(****Name of study sponsor)* is a (*non-profit/for profit research group/drug company)*. *For NCI studies include the following sentence:* This study has public funding from the National Cancer Institute (NCI), part of the National Institutes of Health (NIH) in the United States Department of Health and Human Services. The manufacturer of the study drug is providing the study drug free of charge for use in this study. The researchers at this centre will not receive any direct benefit for conducting this study.

The doctor treating you also may be the doctor in charge of this study.

If you would like additional information about the funding for this study, or about the role of the doctor in charge of this study, please speak to the study staff or to the (ethics board)

***See Instruction Guide.***

1. Where can I get more information?

*If US FDA regulated*

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.

And/or

*For all other trials*

A description of this clinical trial will be available on *(insert full web address).* This website will not include information that can identify you. You can search this website at any time.

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor:

*(Insert name of study doctor[s])* *(Insert telephone number, and email address if appropriate)*

Name Telephone

For questions about your rights while in this study, call the: Office of the Chair of the Ontario Cancer Research Ethics Board at: *416-673-6648 OR Toll free: 1-866-678-6427 ext. 6648*

***See Instruction Guide.*** *Use the following header and adapt the following text for all studies with additional optional studies.*

1. Optional studies that you can choose to take part in

This part of the consent form is about optional studies that you can choose to take part in. Optional studies will either be directly related to the main study or will be for future research not related to the main study. These optional studies will not benefit your health.

The researchers leading *(this optional study / these optional studies)* hope the results will help other people with *(cancer / your condition)* in the future*. (Include the following sentence if appropriate).* The results *(will/ will not)* be added to your medical records and you or your study doctor (*will/will not*) know the results.

Taking part in (*this optional study / these optional studies*) is your choice. You can still take part in the main study even if you say “no” to (*this study / any or all of these studies*). There will be no loss of benefits for saying “no.” If you consent, but cannot complete *(this study / any of these studies)* for any reason, you can still take part in the main study.

Circle your choice of “yes” or “no” for (*the following study/each of the following studies)*

*20a. An extra scan for research purposes: adapt this example as needed.*

Optional imaging study – extra scan

If you choose to take part in this study, you will have an extra *(insert name of standard clinical imaging procedure, e.g., PET scan)*. This scan is already used in medical care. But, in this study, the scan would be done at a different time in your treatment than it would be if you were getting standard of care. Researchers would use this scan to *(briefly describe purpose, e.g., try to learn more about how treatment works on cancer)*. *(Include and adapt one of the two following sentences as appropriate, depending on whether the scan may be used to guide care.)* The scan *(may or would)* be used to guide your medical care.  *(If scan will not guide care, use the following sentence instead.)* The scan would only be used for research and not to guide your medical care.

If you agree to have this extra scan, it would involve *(briefly describe procedures, e.g., blood draw, contrast agent, time)*. The risks would be *(briefly describe risks, focusing on risks of extra scan, e.g., additional radiation risk, risk of contrast)*. Ask your study doctor if you would like to learn more about this type of scan.

Please circle your answer: I choose to take part in the imaging study and will have the extra *(insert name of procedure, e.g., PET scan)*:

YES NO

*20b. An investigational scan or procedure: adapt this example as needed.*

**Optional imaging study – research scan or procedure**

If you choose to take part in this study, you will have an extra *(insert name of standard clinical imaging procedure, e.g., PET scan)*. This scan is already used in medical care and the risks of this standard procedure will be explained to you. In this study, the scan will be done at another time in your treatment than with the standard of care. Researchers would use this scan to (*briefly describe purpose, e.g., try to learn more about how treatment works on cancer*). (*Include and adapt one of the two following sentences as appropriate, depending on whether the scan may be used to guide care.*) The scan (*may or would*) be used to guide your medical care. (*If scan will not guide care, use the following sentence instead.*) The scan would only be used for research and not to guide your medical care.

If you agree to have this extra scan, it would involve *(briefly describe procedures, e.g., blood draw, contrast agent, more time)*. The risks would be *(briefly describe, focusing on risks of extra scan, e.g., additional radiation risk, risk of contrast*. Ask your study doctor if you would like to learn more about this type of scan.

Please circle your answer: I choose to take part in the imaging study and will have the (*insert name of scan or procedure*):

 YES NO

*20c. An optional quality of life study embedded in the main study: adapt this example as needed.*

Optional quality of life study

If you choose to take part in this study, you will be asked to fill out a form with questions about *(briefly state topic, e.g., your physical and emotional well-being).* Researchers will use this information to *(briefly describe purpose, e.g., learn more about how cancer and cancer treatment affects people).*

(Include and adapt the following two sentences as appropriate.) Since these forms are being used for research, the responses you provide will not be shared with your study doctor. If you have any serious health issues or other concerns, please talk with your doctor or nurse right away.

You will be asked to fill out this form at (insert number) times:

* *(insert bulleted list of time indicators, e.g., before surgery, after surgery before chemotherapy, and mode, e.g., inpatient, mail, or phone).*

Each form will take about *(insert number)* minutes to complete. The forms will ask about things like *(briefly describe, e.g., tiredness, diarrhea).* You don’t have to answer any question that makes you feel uncomfortable.

Please circle your answer: I choose to take part in the quality of life study and will fill out these forms:

 YES NO

*See Instruction Guide.*

20d. *“Defined/Known Lab Study (ies)” and/or “Future Unspecified Research”: adapt test below and include both types if appropriate per the protocol.*

Optional sample collections for known laboratory studies and/or storage for possible future studies

Researchers are trying to learn more about cancer and other health problems using blood and tissue samples from people who take part in clinical trials. By studying these samples, researchers hope to find new ways to prevent, detect, treat, or cure diseases.

Some of these studies may be about how genes affect health and disease. Other studies may look at how genes affect a person’s response to treatment. Genes carry information about traits that are found in you and your family. Examples of traits are the color of your eyes, having curly or straight hair, and certain health conditions that are passed down in families. Some of the studies may lead to new products, such as drugs or tests for diseases.

*Include information about all specimens to be collected and all known future studies. Make sure that all optional collections described here align with what is described in the protocol and study calendar.*

*Example for Defined/Known Lab Study (ies)*

Known future studies

If you choose to take part in this optional study, researchers will collect *(insert specimen to be collected, e.g., blood\*)* for research on *(briefly describe purpose*). *(Insert additional sentences describing in plain language the specimen to be collected, the research purpose, and planned analyses such as genetic sequencing for each known study.)*

*Include this required section if specimens are being banked for unknown future studies.*

*Example for a Specimen Collected for Future Unspecified Research*

Unknown future studies

If you choose to take part in this optional study, *(insert specimen to be collected,* *e.g., a sample from your previous biopsy)* will be collected and stored. Storing samples for future studies is called “biobanking.” The biobank is being run by *(insert name)* in *(insert location of biobank- at least country)*. Also, any health-related information, such as your response to cancer treatment, results of study tests, and medicines you took, will be stored for future use.

We will protect your privacy. The goal of biobanking is to make more research possible that may improve people’s health. The biobank has controlled access. This means that researchers who want to get samples and data from it must submit a specific research request. The request identifies who they are and what their planned research project is. Before getting the samples and data, the researchers must agree to keep the data private, only use it for their planned research project, and never use it to try to identify you.

Right now we don’t know what research may be done in the future using your *(blood and/or tissue)* samples. This means that:

* You will not be asked if you agree to take part in the future research studies.
* You and your study doctor will not be told when or what type of research will be done.
* You will not get reports or other information about any research that is done using your samples.

*Select the appropriate text example. This section on Unknown future studies requires one of these examples.*

*20d Example for study collecting tumour tissue)*

Unknown future research studies include sequencing of all or part of your DNA. This is called genomic sequencing. Sequencing allows researchers to identify your genetic code. Changes in your genetic code may just be in your tumour tissue. These are called somatic changes. Changes may also be in your normal tissue and passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair colour are passed down. These are called germline changes. If only tumour tissue is sequenced we will not know if a genetic change in your tumour is also in your normal tissue. This is why sometimes both normal tissue and tumour tissue are sequenced. This helps researchers understand if a genetic change happened only in your cancer tissue or in your normal tissue as well.

*20d Example for study not collecting tumour tissue)*

Unknown future research studies may include sequencing of all of part of your DNA. This is called genomic sequencing. Sequencing allows researchers to identify your genetic code. Changes in your genetic code may be passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair colour are passed down. These are called germline changes.

*Adapt the text below based on the study. The entire section should not be repeated for each sample collection; instead, describe all sample collections – for both known and unknown future research – in item 1 of the “What is involved” section below.*

*For Item 1 of the “What is involved” section, choose the appropriate information from the sentences that follow or add other information as necessary. Describe all study sample(s) and all collection time points. Note if the sample is drawn at same time as other draws, is residual material from embedded correlative, or already exists (archived tissue).*

What is involved in this optional sample collection?

If you agree to take part, here is what will happen next:

1. *(Text example for blood sample.)* About *(insert amount in ml (Imperial measure in parentheses))* of blood will be collected from a vein in your arm. *(Text example for archival tissue sample.)* A sample from the tissue that was collected at the time of (\*insert such as your surgery or your procedure\*) will be sent to the biobank. *(Text example for new tissue sample.)* A sample of tissue will be collected from an optional extra biopsy.
2. *(Include or adapt the following sentences as appropriate.)* Your sample will be stored in the biobank. There is no limit on the length of time we will keep your samples and research information. The samples will be kept until they are used for research or destroyed.
3. Researchers can only get samples from the biobank after their research has been approved by experts*. (Include or adapt the following sentence as appropriate.)* Researchers will not be given your name or contact information.
4. Some of your genetic and health information may be placed in central databases for researchers to use. The databases will not include your name or contact information.

What are the risks in this optional sample collection?

* *(Adapt the following sentence as appropriate to describe risks from the study sample collection.)* The most common risks related to drawing blood from your arm are brief pain and maybe a bruise.
* *(Include and adapt the following sentence as appropriate to describe risks from optional tissue submissions as appropriate for the study.)* Generally, hospitals will keep some of your tissue. This tissue may be used to help treat your cancer in the future.  There is a small risk that when this tissue sample is submitted to the biobank for this optional sample collection, your tissue could be used up.
* Your medical and genetic information is unique to you. There is a risk that someone outside of the research study could get access to your study records or trace information in a database back to you. They could use that information in a way that could harm you. Researchers believe the chance that someone could access and misuse your information is very small. However, the risk may increase in the future as people find new ways of tracing information.

How will information about me be kept private?

Your privacy is very important to the study researchers and biobank. They will make every effort to protect it. Here are just a few of the steps they will take:

1. They will remove identifiers from your sample and information. They will replace them with a code number. There will be a master list linking the code numbers to names, but they will keep it separate from the samples and information.
2. Researchers who study your sample and information will not know who you are. They also must agree that they will not try to find out who you are.
3. Your personal information will not be given to anyone unless it is required by law.
4. If research results are published, your name and other personal information will not be used.

What are the benefits to taking part in this optional sample collection?

You will not benefit from taking part. (*If information may be given to the study participant’s physician for use in their care, insert appropriate information about the return of results*.)

The researchers, using the samples from you and others, might make discoveries that could help people in the future.

Are there any costs or payments to this optional sample collection?

There are no costs to you. You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

What if I change my mind about this optional sample collection?

If you decide you no longer want your samples to be used, you can tell the study doctor, who will let the biobank know. Then, any sample that remains in the biobank will be destroyed or returned to your study doctor. This will not apply to any samples or related health information that have already been given to or used by researchers.

What if I have questions about this optional sample collection?

If you have questions about the use of your samples for research, contact the study doctor.

Agreement to take part in optional *study/studies*

*Use the following sentence if optional studies have been included.*

Please circle your answer below to show if you would or would not like to take part in each optional study:

*Include the following statements as applicable.*

**Samples for known future studies:**

I agree that my samples and related health information may be used for the laboratory *(study or studies)* described above.

 YES NO

*(Include or adapt the following sentence if appropriate.)*

**Contact about results from known future *study/studies***

I agree that my study doctor, or someone on the study team, may contact me or my doctor to see if I wish to learn about results from *(this study or these studies)*.

 YES NO

Samples to be bio-banked for unknown future studies:

I agree that my samples and related health information may be kept in a biobank for use in future health research.

 YES NO

*Use the following text for any studies where participants may be contacted in the future.*

Contact for future research

I agree that my study doctor, or someone on the study team, may contact me or my doctor to see if I wish to participate in other research in the future.

 YES NO

Use the following sentence if optional studies have been included.

This is the end of the section about optional studies.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*21. Signature section: See Instruction Guide.*

My signature agreeing to take part in the study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in the main study. *(Include the following sentence if appropriate.)* I also agree to take part in any additional studies where I circled “yes”.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant Printed Name Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Conducting Printed Name Date

the Consent Discussion

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Parent/Guardian Printed Name Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Parent/Guardian Printed Name Date

Participant Assistance

**Complete the following declaration only if the participant is unable to read:**

* The informed consent form was accurately explained to, and apparently understood by, the participant, and,
* Informed consent was freely given by the participant.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Impartial Witness Printed Name Date

**Complete the following declaration only if the participant has limited proficiency in the language in which the consent form is written and interpretation was provided as follows:**

* The informed consent discussion was interpreted by an interpreter, and,
* A sight translation of this document was provided by the interpreter as directed by the research staff conducting the consent.

Interpreter declaration and signature: By signing the consent form I attest that I provided a faithful interpretation for the discussion that took place in my presence, and provided a sight translation of this document as directed by the research staff conducting the consent.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Interpreter Printed Name Date