# Instructions for OHSN-REB Oncology Clinical Trial Informed Consent Form Template

This Onclology Clinical Trial Informed Consent Form (ICF) Template has been designed to meet current regulatory and ethical standards. The study ICF must be uploaded into the OHSN-REB IRIS Application and should follow the prescribed structure and format as set out in this template.

**Tips for Writing and implementing the consent**

* Delete this instructional page
* Use plain (lay) language that is easy for a non-medical person to understand:
  + Use short sentences and sections and simple words; avoid scientific or technical explanations;
  + Ensure that the final form is properly formatted and free of spelling or grammar errors;
  + Aim for grade 8 reading level, ideally no more than grade 10;
  + Spelling, grammar and formatting should be reviewed prior to submission
  + Eliminate repetition of information, the study drug should be named
* Define all acronyms and abbreviations when they first appear
* Use the term ‘study doctor’ when referring to physicians involved in the clinical trial/study, to ensure there is no confusion with the treating or primary care doctors
* If assistance is provided during the consent process, or if consent is obtained from substitute decision maker, more information, including the role or relationship of the impartial witness/interpreter/substitute decision maker, should be noted in the medical record and/or study record.

**HOW TO USE THIS TEMPLATE**

* *Turquoise italicized highlighting* indicates instructions to consent form authors; DELETE from final.
* *Blue italics* within sentences indicate that protocol-specific detailsneed to be inserted, such as drug/intervention name, descriptions, options for protocol details; REPLACE italics with regular font.
* Suggested text/examples are provided throughout ICF; they should be omitted if they are not relevant to the specific protocol.
* Consider including two study titles:

**Lay Title for Study Participants** is a reader-friendly lay version of the study title:

* + Provide a brief (<20 words) title of the study in lay language
  + Make title concise; list the usual approach in generic terms (chemotherapy, radiation therapy, surgery), rather than specific names (IMRT, laparoscopy)
  + Use a size and font of text that is consistent and easy to read (size 11 or larger is recommended)
  + After all edits have been made, all text should be black

STUDY TITLE refers to official title which can be used by potential participants for Internet searches

* + Insert trial code (XX.XX) and official study title as provided by the study sponsor
  + Do NOT use Bold font. Use size 9 pt. font and ALL CAPS

**REMINDER:** The informed consent form is only a component of the informed consent process. Researchers still need to have an informed discussion with, and respond to any questions raised by, participants.

**Informed Consent Form for Participants in an Oncology Research Study**

***Lay Title for Study Participants:*** *(maximum 20 words)*

***STUDY TITLE:****insert study title as written on the protocol*

**OHSN-REB Number:** *insert number*

**Sponsor Study ID:** *Insert sponsor’s study ID if applicable*

**Study Doctor:** *insert name, department and telephone or pager number*

**Sponsor/Funder(s):** *Insert the name of the Sponsor or, if applicable, the funder(s) of the research*

[Note: A 24-hour, 7-day a week phone number is required for all studies that include greater than minimal risk research procedures or interventions.]

**Emergency Contact Number** (24 hours / 7 days a week): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Non-Emergency contact numbers are at the end of this document under Contacts.

*Le formulaire de consentement est disponible en français sur demande.*

**Introduction**

You are being invited to participate in a clinical trial (a type of study that involves research). Clinical trials only include participants who choose to take part. You are invited to participate in this trial because you have *explain the main features of the population to which the research applies.* This consent form provides you with information to help you make an informed choice. Please read this document carefully and take your time in making your decision. You may find it helpful to discuss it with your friends and family.

Taking part in this study is voluntary. You may choose not to take part or if you choose to participate may leave the study at any time without giving a reason. Deciding not to take part or deciding to leave the study later will not result in any penalty or any loss of benefits to which you are entitled.

**Background**

*Note: this section should reflect standard or usual treatment, if applicable*

The standard or usual treatment for your disease is *describe the standard treatment*.

*If applicable:*

*Agent generic name (compound name*) is a new type of drug for *disease site cancer.* Laboratory tests show that it may help slow the growth of *disease site cancer. Agent has been shown to shrink tumours in animals/has been studied in a few people and seems promising* but it is not clear if it can offer better results than standard treatment.

Health Canada, the regulatory body that oversees the use of drugs in Canada, has not approved the sale or use of *agent* to treat this kind *and/or stage* of cancer, although they have allowed its use in this study.

**Purpose**

*Include one of these paragraphs for Phase I Studies:*

The purpose of this study is to test the safety of a new drug, *agent,* to see what effects it has on you and your *disease site cancer*.

*or*

The purpose of this study is to find the highest dose of a new drug, *agent*,thatcan be tolerated without causing very severe side effects. This is done by starting at a dose lower than the one that does not cause side effects in animals. Participants are given *agent* and are watched very closely to see what side effects they have and to make sure the side effects are not severe. If the side effects are not severe, then new participants will be given a higher dose of *agent*. Participants joining this study later on will get higher doses of *agent* than participants who join earlier. This will continue until a dose is found that causes severe but temporary side effects. Doses higher than that will not be given.

*For Phase II Studies:*

The purpose of this study is to find out what effects a new drug, *agent,* has on you and your *disease site cancer*.

*For Phase III Studies:*

The purpose of this study is to compare the effects on you and your *disease site cancer* of a new drug, *agent,* compared to other drugs which are commonly-used drugs to treat this disease.

*For Phase III Placebo Controlled Studies:*

The purpose of this study is to find out *specify purpose: e.g., whether it is better to receive a new drug, agent, or better to receive no further treatment for (cancer type)*. To do this, some of the participants in this study will get *agent* and some will receive a placebo (a substance that looks like the study drug but does not have any active or medicinal ingredients).

**Alternative Treatments**

You do not have to take part in this study in order to receive treatment/care. Other options (in addition to the standard or usual treatment described above) may include, but are not limited to:

*Include bulleted items of applicable treatment; add others as needed; delete those that do not apply.*

* No therapy at this time.
* Palliative care or best supportive care (BSC). This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Best supportive care tries to keep you as active and comfortable as possible.
* Other experimental studies may be available if you do not take part in this study.

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

**Expected Number of Participants**

*Phase I/II study:*

Up to *X* people will take part in this study.

*Phase III example:*

About *X* people from *Canada, United States and other countries* will take part in this study.

*For ALL Phases enter protocol-specific information:*

This study should take *x years* to complete and the results should be known in about x years.

Your study doctor will be informed of the results of this study once they are known.

**Assignment to a Group**

*For randomized, blinded or un-blindedtrials:*

If you decide to participate then you will be "randomized" into one of the groups described below. Randomization means that you are put into a group by chance *like flipping a coin/rolling dice*. There is no way to predict which group you will be assigned to. You will have *an equal/a one in three, etc.* chance of being placed in *either/any* group. Neither you nor your study doctor can choose what group you will be in.

*For randomized non-blinded trials include*

You will be told which treatment you are to get.

*For randomized blinded trials include*

This is a double-blind study, which means that neither you nor your study doctor will know which treatment you are receiving. Your treatment will be identified if medically necessary. Requests to unblind/find out which treatment you are receiving for any other reason will not be considered until this study has been completed and the results are known.

*For trials with treatment assigned based on protocol-specific criteria*

If you decide to participate, then you will be assigned into one of the groups described below. The group you are assigned to will be determined by *specify assignment criteria: e.g. the stage of cancer you have and the cancer treatments you have previously received*.

You will be told which treatment you are to get.

*For phase I or II studies:*

**Experimental Treatment**

If you agree to take part in this study, you will be given *agent -* *describe method: e.g. by needle into one of your veins, orally*. The procedure will take about *<X>* minutes. This will happen every *<X>* weeks for *<X>* months. The dose may be changed if you have side effects. You will not need to be hospitalized unless you have serious side effects.

*If applicable, prophylactic or other protocol mandated treatments (e.g. antiemetic) to be given prior to or following chemotherapy etc. should be described and identified as Experimental or Non-Experimental*

*For randomized studies:*

**Group 1 (Experimental Treatment):**

Standard Chemotherapy *specify drug name/regimen/treatment* plus *the experimental agent name/regimen/treatment*

If you are randomized to Group 1 you will receive two commonly-used chemotherapy drugs called *agent* and *agent* plus you will be given the experimental drug/*agent*. These drugs will be given into one of your veins by needle every *<X>* days for *<X>* visits. The procedure will take about *<X>* hours. The doses of the drugs may be changed if you have side effects.

**Group 2 (Non-Experimental Treatment):**

Standard Chemotherapy *specify drug name/regimen/treatment*

If you are randomized to Group 2 you will receive two commonly-used chemotherapy drugs called *agent* and *agent*. These drugs will be given by needle into one of your veins every *<X>* days for *<X>* visits. The procedure will take about *<X>* hours. The doses of the drugs may be changed if you have side effects.

**Study Procedures**

*Describe the procedures that are used in the study, including clear identification of those procedures that are experimental. It is not necessary to describe the risks associated with tests or procedures with which the participant population would already be familiar*

**Experimental Procedures**

*Only include experimental tests or procedures that are being tested as part of this study. Any standard procedures (e.g., MRI, blood draw, etc.) that are outside of standard of care should be included in the ‘non-experimental procedures’ section – this section is for procedures that are experimental (e.g., not validated) being tested as part of the research. Explain any risks of experimental procedures and medical tests in the risk section*

The following test(s) is/are considered experimental and will only be done for participants on this study:

* *List the experimental test(s) or procedure(s) being studied in this trial; explain what each test or procedures involves and the purpose/reason/rationale for including it in the research*

*If applicable include:*

If the results of the test(s) show that you are not able to continue participating, your doctor will let you know.

*For all studies:*

**Non-Experimental Procedures**

The following tests will be done as part of this study. Some of these tests may be done as part of your standard care, in which case the results may be used. Some of these tests may be done more frequently than if you were not taking part in this study and some may be done solely for the purpose of the study. If the results show that you are not able to continue participating, your study doctor will let you know:

*Examples (delete tests that are not applicable, remove italics from those included):*

* Mammogram
* Blood/urine tests

*Standard* *liver function, biochemistry, and other routine blood tests done as part of standard of care do not need to be specified or individually listed. If other tests (such as HIV, Hepatitis) are being done for study purposes only, they should be specified]*

*If applicable:*

* HIV Testing

This study involves testing to determine your HIV status. This test is required for this research study to find out if *provide reason for the test if not described elsewhere in the consent – e.g., you meet the eligibility requirements, etc*. If you test positive for HIV, you *will not/will* be able to participate in this study.

In order for you to be tested for HIV you will need to provide a separate consent for the testing. Before providing your consent you should know that you have the option of going to an anonymous HIV test site to get your test results privately, and you can choose not to share this information. If you consent to be tested for the study, the results of your HIV tests, like all other laboratory test results, will be provided to the Sponsor, your study doctor and your usual doctor.

If you test positive, your doctor will be required to share your identity and your HIV status with Public Health. The people you may have exposed to HIV will have to be notified either by you, your usual doctor or by Public Health.

If you have concerns about being tested for HIV and the consequences of testing positive, you should speak to your study doctor or your usual doctor before providing your consent to be tested.

*Standard tests performed as part of a physical examination do not need to be specified. If other tests are done for study purposes only, they should be specified*

* Physical examination
* Pregnancy test
* Chest x-ray
* Magnetic Resonance Imaging (MRI) *–* 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 dye is used for the procedure, include: MRI scans often involve injecting a dye into your vein*
* Computed Tomography (CT) scan – 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.
* X-rays of your bones (skeletal survey)
* A special x-ray to study the heart (MUGA scan)
* Insertion of a central venous catheter (also called central venous line, central line or central catheter). This is a small tube attached to a needle which is inserted into a large vein (in the neck, chest or groin) that leads to the heart. It allows easy access to veins for taking blood and giving medications and transfusions through the small tube so that you do not need a needle poke each time.
* Positron Emission Tomography (PET ) – 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.

*If applicable:* ***for centres*** *for which certain treatments, tests or procedures (e.g., scans) may take place at another location* ***please include the following information*** *with applicable modifications*

The following *treatments/procedures/* *tests* for this study may take place *closer to your home/at another location*. [*name of centre/location to be entered if applicable*]

The *information/results from these* *treatments/tprocedures/tests* will be sent to your study doctor.

* List the treatments/ tests procedures that are authorized to take place at the above location/centre

*If applicable:*

**Questionnaires**

You will be provided with a questionnaire before starting this study, and then every *specify details such as:* *x months while you are receiving treatment and x times a year after treatment up to x years*. The purpose of the questionnaire is to understand how your treatment and illness affects your quality of life. Each questionnaire will take about *x minutes* to complete.

*Include if instructions are not included on the questionnaire:*

The information you provide is for research purposes only and will remain strictly confidential.

Some of the questions are personal; you may choose not to answer these if you wish.

*If the questions are of a sensitive nature, explain that the participant might experience emotional distress, in which case explain what should they do and what type of help will be provided if this happens.*

Even though you may have provided information on a questionnaire, these responses will not be reviewed by your health care team or study team. If you wish them to know this information please bring it to their attention.

*If participant diaries are protocol-mandated include the following:*

**Participant Diaries**

You will be asked to keep a diary of when you take your study medication. Please record the exact time of taking each dose in your daily diary. You will be asked to return the diary to the clinic/hospital.

*If applicable:*

**Central *specify type of review: e.g., Radiology, Radiotherapy, Surgical* Review**

Copies of your *specify material being submitted e.g., scan type e.g. CT or MRI* will be collected as part of this study. This is required for quality assurance and data management. The copies will be sent to *specify location where the review will be conducted review e.g., City, Country*, and kept until the end of the study monitoring period *or specify other retention period* when then they will be destroyed.

To protect your identity, the information that will be on your *specify: e.g. scans* will be limited to *specify which identifiers will be on the sample(s)*. *If the sponsor requires the participant's initials to be part of the participant's study code, add* which may include your pseudo-initials. *Identifiers such as "patient or hospital identification number" may not be used*.

**Mandatory Sample Collection**

*If applicable, mandatory samples are only acceptable as "mandatory" if they are collected for the purpose of either determining eligibility or for a pre-defined study objective, otherwise it is considered optional. The samples only may be kept for the period of time required to conduct these tests and any leftover samples must be either returned to the facility from which they were obtained if needed, or destroyed. Samples only may be banked for other future research if the participant signs an optional consent form for banking. Sample collection that is optional (including banking for other future research), must not be part of the main consent and should instead be covered by a separate "optional" consent form. The availability of this option may be mentioned in the consent (see below).*

The researchers doing this study need to do tests on samples (described below) to make sure you have the type of cancer that is being studied and/or to see how the cancer cells respond to the *study drug*.The purpose of this sample collection is *provide study specific explanations of the research for all sample types (blood and tissue).*

*If hereditary genetic testing will be done include the following: Hereditary genetic testing (to find out if cancer runs in your family) will/may be done on these samples.*

*If hereditary testing will not be done on the samples include the following: Hereditary genetic testing (to find out if cancer runs in your family) will not be done on these samples.*

The collection of these samples is a necessary part of this study and will be used only for these purposes. The samples will not be sold. Once these tests have been completed, any leftover samples will be returned to the facility from which they were obtained if needed or destroyed, unless you wish to give permission for other future research purposes, in which case you will be given a separate optional consent form to sign. If you participate in this study it is possible that not enough tumour tissue will be left for other testing that may need to be done in the future. Please speak to your study doctor to discuss this possibility.

Certain types of genetic testing could have implications for you or your biological relatives.  The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

Please ask your study doctor whether this might apply to you as a result of your participation in this study.

*If applicable:*

Reports about any research tests done with your samples will not be given to you or your study doctor. These reports will not be put in your medical records.

If you are a First Nations or an indigenous person who has contact with spiritual 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.

*If applicable describe process of tissue collection here:*

**Tissue Collection (Required)**

A small sample of your tumour that has already been removed by a previous surgery or biopsy will be obtained by the researchers doing this study. No further surgeries or biopsies are required of you for this purpose. If your biopsy or surgery were completed at another institution, signing this consent form means that you are consenting to the collection of your tissue sample, together with any related personal health information, from that institution. *If applicable, explain whether participants may still participate if a sample is not available or whether a fresh tissue sample will then be required – see below.*

*If a fresh tissue sample is required:*

If a previous tissue sample is not available, you will need to have a tissue biopsy. A tissue biopsy is a type of surgical procedure, which will remove *state how much tissue is to be taken e.g. a pea size piece* of your *insert type of cancer* cancer. *Explain in lay language whether this will be done using a local or general anesthetic and whether overnight hospital stay may be required.* This procedure has risks such as blood loss, pain and rarely an infection at the biopsy site.

These tissue samples will be sent to a laboratory at the *Institution, City, Country (minimum required location is Country)* where they will be examined to confirm your diagnosis *or explain the purpose*.

*If applicable:*

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

Urine will be collected *specify number of samples to be collected and timing (e.g., specify if 24 hour collection) and if additional samples are required.* These urine samples will be sent to a laboratory at the *Institution, City, Country (minimum required location is Country)* where they will be examined to *explain the purpose*.

Blood samples will be taken by inserting a needle into a vein in your arm. These will be taken at the same time as your study related tests whenever possible e.g. at entry to the study and <X> weeks after you go off study. *Specify amount of blood to be collected and timing if additional samples are required and the tests to be done on these samples*. These blood samples will be sent to a laboratory at the *Institution, City, Country (minimum required location is Country)* where they will be examined to confirm your diagnosis *or explain the purpose*.

**Identification of Samples**

*[NOTE: Identifiers such as "patient or hospital identification number" may not be used. If tissue samples leaving the centre are identified with pathology identification number, it must be specified amongst the identifiers below.]*

To protect your identity, the information that will be on your samples will be limited to *specify which identifiers will be on the sample(s).* *For example, participant's study code,pseudo- initials, pathology identification number.*

**Withdrawal of Required Samples**

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.

*State whether or not the participant may continue to participate in this main part of the study, if they withdraw these required samples.*

*If applicable:*

**Optional Sample Collection and Banking**

The researchers doing this study are interested in doing additional research *now or in the future on the samples collected from you*. You will be given an additional optional study consent form to read and sign if you wish to give permission *for the samples to be banked (stored) for future research purposes*. You may decide not to participate in the "optional" study and still participate in this main study.

**Responsibilities**

*Examples (delete ones that are not applicable/ add additional items as needed):*

If you choose to participate in this study, you will be expected to:

* Tell your study doctor about your current medical conditions;
* Tell your study doctor about all prescription and non-prescription medications and supplements, 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;
* Tell your study doctor if you are thinking about participating on another research study;
* Return any unused study medication;
* Return any diaries or questionnaires that were completed to the clinic/hospital;
* Tell your study doctor if you become pregnant or father a child while participating on this study; *(include this only if applicable)*
* *Avoid drinking/eating: specify what and for how long*

**Length of Participation**

Your treatment will last for about *<X> months if you are randomized to Group 1. If you are randomized to Group 2, your treatment will last for about <X> months*.

You will be asked to come back to the clinic/hospital *<X> days after the last dose of study treatment. You will then be asked to come back every <X> months for <X> years*.

You may be seen more often if your study doctor determines that this is necessary, or if your cancer *specify: comes back/gets worse*.

*Note: indicate the overall length of time required beyond that of the standard or usual care - specifying the difference in the number of visits and the length of time for each visit plus the time needed to complete questionnaires or diaries.*

No matter which group you are randomized to, and even if you stop treatment early, the researchers would like to keep track of your health *define period of time* to look at the long-term effects of your participation on this study. This would be done by *specify follow-up method and frequency: e.g., contacting you for a follow up visit; contacting you by phone.*

**Early End to Participation**

Your participation in the trial may be stopped early, for reasons such as:

* The treatment does not work for you and your cancer *specify: comes back/gets worse*.
* You are unable to tolerate the study treatment.
* You are unable to complete all required study procedures.
* New information shows that the study treatment is no longer in your best interest.
* Your study doctor no longer feels this is the best treatment for you.
* The sponsor decides to stop the study.

*Include reference to regulatory authorities only* *if trial under a CTA*

* A Regulatory authority such as Health Canada or the Ottawa Health Science Network Research Ethics Board withdraws permission for the study to continue.

*include these statements only if applicable*

* Your treatment assignment becomes known to you or your study doctor.
* If you become pregnant.

If your participation in the study is stopped your study doctor will provide information about how to stop safely.

**Risks of Participation**

Participating in this study will put you at risk for the side effects listed below. You should discuss these with your study doctor. As with any treatment additional unexpected and sometimes serious side effects are a possibility.

Your study doctor will watch you closely to see if you have side effects. When possible, other drugs will be given to you to make side effects less serious and more tolerable. Many side effects go away shortly after your treatmentis stopped but in some cases side effects can be serious, long-lasting, permanent, or may even cause death.

*For studies using non-marketed drugs or other investigational interventions if applicable:*

If you experience serious side effects that require treatment between regular clinic/hospital visits, it is important that you make every effort to return to the clinic/hospital where *agent* was given. Because *agent* is an experimental drug and is only used in clinics/hospitals involved in research studies, any serious side effects of the drug may be best treated by these clinics/hospitals. If you need immediate treatment and are unable to return to the clinic/hospital where *agent* was given, you should go to the nearest medical clinic/hospital and tell them that your study doctor should be contacted as soon as possible.

***Agent Name***

Risks and side effects related to the experimental *drug/procedure/agent* being studied include:

*use NCI US template for risk categorization or a recognized alternative - e.g., CIOMS*

*Very likely (21% or more, or more than 20 people in 100):*

* *list risks*

*Less likely (5– 20% or between 5 and 20 people in 100):*

* *list risks*

*Rarely (1 – 4% or less than 5 in 100 people):*

* *list risks*

*When limited numbers of individuals have been exposed to the drug (less than 100), and the risks cannot accurately be quantified, the following language 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*.

*If the study drug will be used in combination with non-experimental treatment/therapy, the consent should include the following:*

You will receive the standard treatment for the type of cancer you have however, an experimental drug is being added to this standard treatment. The combination could change/increase side effects or the effectiveness of the standard treatment.

*It is not necessary to include a list of risks or side effects of standard treatment if given alone, however the following statement should be included:*

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

It is possible that other drugs (prescription and non-prescription drugs), vitamins, or herbals can interact with the drugs used in this study. This can result in either the drugs not working as expected or result in severe side effects.

*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.

*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:*

**Radiation Risks**

i) Greater or equal than 0.1 and under 2.7 mSv:

“The additional amount of radiation you will receive from participating in this research study is about the same amount a person would receive naturally, while living in Ontario for <<>> months. The risk is considered to be negligible.”

ii) Greater or equal than 2.7 mSv and under 20 mSv:

“The additional amount of radiation you will receive from participating in this research study is about the same amount a person would receive naturally, while living in Ontario for <<>> years. The risk is considered to be minimal and there are no expected consequences associated with this exposure.”

iii) Greater or equal than 20 mSv and under or equal to 50 mSv:

“The additional amount of radiation you will receive from participating in this research study is about the same amount a person would receive naturally, while living in Ontario for <<>> years. The overall risk is considered to be acceptable and there are no expected consequences associated with this exposure.”

iv) Above 50 mSv:

“The additional amount of radiation you will receive from participating in this research study is approximately <<>> % of the average natural lifetime exposure in Ontario. The overall risk is considered to be acceptable and there are no expected consequences associated with this exposure. Doses to individual organs are listed and can be discussed with your physician.”

**Risk of Insurability**:

There is a possibility that participation in research may affect your insurability under certain insurance policies.

**Reproductive Risks**

*The effects that agent* *may have on an unborn baby (fetus) are unknown OR the study drugs may harm an unborn baby (fetus).* You must not *specify: become pregnant / father a baby* while taking *agent* and for *<X>* months after the last dose.

*If applicable: If there are known interactions or contraindications with specific methods, they should be included.*

Your study doctor will discuss methods with you to ensure that you do not *specify: become pregnant or father a baby* during the study.

Women should not nurse (breastfeed) a baby while taking study treatment and for *<X>* months after the last dose because the drugs used in this study might be present in breast milk and could be harmful to a baby.

*For trials with pregnancy reporting, please include the following as applicable:*

If you become pregnant or father a child during this study or for *specify duration* after you stop taking the study drug, then you should immediately notify your study doctor. Your study doctor will let the sponsor know about the pregnancy.

*If applicable add the following*

If you become pregnant, the researchers or sponsor for this study will access information on the outcome of the pregnancy. This information will be gathered from your medical/study record.

*If applicable add the following:*

This also may involve contacting you *specify duration – e.g., every x months* *for the next* *specify duration* *– e.g.,* *x* years to ask about the health of your child. The researchers or sponsor also may ask to contact the child’s father to get information related to the pregnancy. If you become pregnant and do not want the researchers/sponsor to collect this information, you must let your study doctor know.

*If applicable add the following*

If you father a child, the researchers or sponsor for this study will ask to contact the child’s mother to collect information on the outcome of the pregnancy. The child’s mother will be given a separate consent document to sign to give permission for the collection of this information, if a pregnancy should happen. This also may involve contacting the child’s mother *specify duration – e.g., every x months* for the next *specify duration – e.g., x years* to ask about the health of the child.

The child’s mother may choose not to give consent for the collection of this information or may withdraw their consent at any time without giving a reason. This will not impact your participation in the study and will not result in any penalty or any loss of benefits to which you are entitled.

*The pregnant partner consent form should be submitted to the REB for review and approval only when/if required [i.e., as an amendment].*

*If applicable:*

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.

# *For Phase III studies only (or IND studies when applicable):*

# **Data Safety Monitoring Board/Committee**

A Data Safety Monitoring Board/Committee, an independent group of experts, will be reviewing the data from this research throughout the study.

**Benefits**

If you agree to take part in this study, the experimental treatment may or may not be of direct benefit to you. *For placebo controlled studies add: If you are randomized to receive a placebo only, you are not expected to benefit.* The researchers hope the information learned from this study will help other patients in the future.

**Confidentiality**

*If there will be a disclosure of personal identifiers i.e., disclosed on research-related information/documents, including samples and scans or as part of the unique identifier, - these disclosures must be justified in the REB application and approved. Please ensure that you are aware of all institutional and REB policies with respect to the disclosure of personal identifiers; specifically date of birth and initials. If the REB or institution mandates the disclosure only of partial date of birth (year/month), and/or of scrambled/coded pseudo-initials, this will be accepted.*

Records identifying you at this centre will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Studies involving humans now routinely collect information on race and ethnicity as well as other characteristics of individuals because these characteristics may influence how people respond to different medications. Providing information on your race or ethnic origin is voluntary.

Authorized representatives of the following organizations may look at your original (identifiable) medical/clinical study records at the site where these records are held, for quality assurance (to check that the information collected for the study is correct and follows proper laws and guidelines):

*Delete any examples below that do not apply*

* *for Industry sponsored studies -* *Company Name,* the sponsor of this study; OR, for cooperative group or academic sponsors - *Organization Name,* the research group coordinating this study;
* *include any other cooperative group or affiliates working with the sponsor and their role*;
* The Ottawa Health Science Network Research Ethics Board, which oversees the ethical conduct of this study in your clinic/hospital;
* The Ottawa Hospital Research Institute, because they oversee the conduct of clinical research studies at your hospital;
* The company or organization that makes the drug *agent*;
* Health Canada, because they oversee the use of drugs in Canada;
* U.S. Food and Drug Administration, because they oversee the use of drugs in the U.S.;
* National Cancer Institute of the U.S., the organization that oversees U.S. participation in this study;
* *LIST other applicable regulatory authorities*

Authorized representatives of the above organizations *if applicable add - and the organizations listed below* may **receive** information related to the study from your medical/clinical study records for quality assurance and data analysis. Your name or other information that may identify you will not be used. The records received by these organizations may contain your *disclose identifiers e.g., participant code, pseudo-initials, sex, partial date of birth*:

*Delete any examples below that do not apply, or list additional organizations:*

* The Cancer Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials;
* *List other regulatory authorities as applicable* because they oversee the use of drugs in other countries*;*

*for trials with tissue collection for the confirmation of diagnosis, radiological review etc*.

* Central laboratories or central review centres

All of the organizations listed in the above confidentiality sections are required to have strict policies and procedures to keep the information they see or receive about you confidential, except where disclosure may be required by law. The study doctor will ensure that any personal health information collected for this study is kept in a secure and confidential location as required by law. There are federal and provincial laws that these organizations must comply with to protect your privacy.

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be used in analyses and will be published/ presented to the scientific community at meetings and in journals. *if applicable include: This information may also be used as part of a submission to regulatory authorities around the world to support the approval of drugs used in this research.*

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

A copy of this signed and dated consent form may be included in your health record/hospital chart.

Your family doctor/health care provider will be informed that you are taking part in a study so that you can be provided with appropriate medical care. If you do not want you family doctor/health care provider to be informed, please discuss with your study doctor.

A wallet card will be provided to you with information about how to contact the study staff when required.

*If data or samples will be sent outside of Canada:*

You should be aware that privacy protections may differ in other countries. Any information *and/or samples if applicable* sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries dealing with protection of information may not be as strict as in Canada. However, all study data *and/or samples if applicable* that are transferred outside of Canada will be coded (this means it will not contain your personal identifying information such as your name, address, medical health number or contact information). Any information will be transferred in compliance with all relevant Canadian privacy laws. By signing this consent form, you are consenting to the disclosure of your coded information to organizations located outside of Canada.

Your de-identified data from this study may be used for other research purposes. If your study data is shared with other researchers, scientific journals, or deposited in an online repository, information that links your study data directly to you will not be shared.

If information from this study is published, shared, or presented at scientific meetings, your name and other personal information will not be used.

**Registration Of Clinical Trials**

For US FDA-regulated studies

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.

This research study can be found on the above listed website by using the clinical trial registration number [insert clinical trial registration number]. (*note: the NCT# must be inserted into the final REB approved participant informed consent form)*

For all other trials:

A description of this clinical trial/study will be available on will be available on <http://www.clinicaltrials.gov>. This website will not include information that can identify you. You can search this website at any time.

This research study can be found on the above listed website by using the clinical trial registration number [insert clinical trial registration number]. (*note: the NCT# must be inserted into the final REB approved participant informed consent form)*

**Costs**

The study drug, *agent*, will be given to you free of charge unless the following occurs:

* You stop participating in this study;
* The drug is no longer provided for this study. If this occurs, you or your insurance company may have to pay for the drug.

Your study doctor will discuss these options with you, as well what will happen if there is no more drug available.

The *identify study agent supplier* will supply the *agent(s)* at no charge while you take part in this study.

Even though it probably won't happen, it is possible that the manufacturer may not continue to provide the *agent(s)* to the *name of study agent supplier identified in first sentence* for some reason.

If this would occur, other possible options are: *include the following as applicable or modify*

* You might be able to get the *agent(s)* from the manufacturer or your pharmacy but you or your insurance company may have to pay for it.
* If there is no *agent(s)* available at all, no one will be able to get more and the study would close.

If a problem with getting the *agent(s)* occurs, your study doctor will talk to you about these options.

*Explain whether or not participants who are benefiting from the experimental treatment will continue to receive the treatment after the study is finished. Wording may be altered according to the type of study or drug, or omitted in the case of adjuvant trials.*

*Even after the study is completed, if the study doctor feels that you are benefiting from the experimental treatment you will continue to be provided with agent(s).*

The costs of your 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.

Taking part in this study may result in added costs to you (i.e. transportation, parking, meals, or unpaid leave from work). You may have to pay for medication prescribed to treat or prevent side effects, and you may have to visit the hospital more often than if you were not participating in this study.

**Compensation**

You will not be paid for taking part in this study.

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

*Note: this statement may be removed/revised as per centre requirements.*

It is possible that the research conducted using your samples and/or study data may eventually lead to the development of new diagnostic tests, new drugs or other commercial products. There are no plans to provide payment to you if this happens.

In the case of research-related illness or injury, medical care will be provided by your doctor or you will be referred for appropriate medical care.

**Rights**

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

If you decide to stop participating in the study or if your participation has been stopped, your doctor will discuss other options with you and continue to treat you with the best means available.

*Participants cannot be required to submit a request for withdrawal in writing. Describe any consequences of withdrawal from the study.*

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 rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

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.

You will be given a copy of this signed and dated consent form prior to participating in this study.

**Conflict of Interest**

*Please include details of any actual or potential conflict of interest concerning this study****.***

This centre is receiving funds from *insert source of funds* to help offset the costs of conducting this research. *name of study sponsor* is a *non-profit/for-profit research group/drug company*, which is the manufacturer of the study drug, and 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 the 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 Chair of the Ottawa Health Sciences Network – Research Ethics Board (contact information below).

**Contacts**

If you have questions about taking part in this study, or if you suffer a research-related injury, you should talk to your study doctor. Or, you can meet with the doctor who is in charge of the study at this institution. That person is:

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Principal Investigator Name |  | Telephone |

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. Please contact The Ottawa Health Science Network Research Ethics Board, Chairperson at 613-798-5555 extension 16719.

**Study Title**: *insert study title as written on the protocol*

SIGNATURES

* All my questions have been answered,
* I understand the information within this informed consent form,
* I have read, or someone has read to me, each page of this participant informed consent form.
* I allow access to my medical records and specimens as explained in this consent form,
* I do not give up any of my legal rights by signing this consent form,
* I am aware of the risks to me of participating in the study and the risks to the fetus if I become pregnant or father a child during this study,
* I understand that my family doctor/health care provider will/may be informed of my participation in this study by the study team, or may learn of my participation when reviewing my electronic health record,
* I agree, or agree to allow the person I am responsible for, to take part in this study.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Signature of Participant |  | Printed Name |  | Date |

**Investigator or Delegate Statement**

I have carefully explained the study to the study participant. To the best of my knowledge, the participant understands the nature, demands, risks and benefits involved in taking part in this study.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Signature of Person Conducting the Consent Discussion |  | Printed Name and Role |  | Date |

**Study Title**: *insert study title as written on the protocol*

**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 any 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 |

*Please note: More information regarding the assistance provided during the consent process should be noted in the medical record for the participant if applicable, noting the role or relationship of the impartial witness.*