# Instructions for Informed Consent Form Development

## The informed consent form (ICF) is only a component of the informed consent process which includes an informed discussion with, and responses to, any questions raised by, the participant. This ICF template has been designed to meet current regulatory and ethical standards.

**TIPS FOR WRITING AND IMPLEMENTING THE CONSENT:**

* Use plain (lay), concise language that is easy for a non-medical person to understand:
  + Use short sentences and sections and simple words; avoid scientific or technical explanations;
  + Aim for grade 8 reading level, ideally no more than grade 10;
  + Refer to lay [glossary](http://humansubjects.stanford.edu/new/docs/glossary_definitions/lay_language.pdf) as needed.
* Eliminate repetition of information.
* Define all acronyms when they first appear and limit their use.
* Use the term ‘study doctor’ when referring to physicians involved in the clinical trial, to ensure there is no confusion with the treating or primary care doctors.
* If assistance is provided during the consent process, more information, including the role or relationship of the impartial witness/interpreter, 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 draft.
* *Blue italics* within sentences indicate that protocol-specific detailsneed to be inserted, (by the provincial applicant) such as drug/intervention name, descriptions, options for protocol details; REPLACE italics with regular font.
* *Yellow italicized highlighting*indicates instructions for participating centres to follow when creating their local ICF. DELETE highlighting from final draft and add information if applicable – i.e., retain in provincial ICF for deletion by centres.
* When developing a local ICF, participating centres should insert the centre-specific information; the highlighting should be deleted from the local ICF.
* Suggested text/examples are provided throughout ICF; they should be omitted if they are not relevant to the specific protocol.
* DELETE this instruction page from final draft.
* The Provincial ICF 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.
* 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)
  + The study drug should be named
  + Use **Bold** font, size 12 pt. Title Case/Font
  + Capitalize Key Words for Easier Reading

STUDY TITLE refers to official title which can be used by potential study 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

***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 CONSENT/PARENTAL/GUARDIAN PERMISSION FORM**

***Lay Title for Study Participants***

STUDY TITLE

*[Note: Sometimes the study design may suggest the use of separate consents. If there is more than one consent, include the “arm” or phase here.]*

Study Number: [insert study number]

Study Doctor: Dr. [Name]

Sponsor: Children’s Oncology Group (COG)

**Emergency Contact Number** (24 hours / 7 days a week): [insert telephone number]

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

Non-Emergency contact numbers are noted at the end of this document under the section heading “Contacts”.

If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say “you” in this consent form, we mean you or your child; “we” means the doctors and other staff.

**Why am I being invited to take part in this study?**

You are being invited to participate in this research study because you have been diagnosed with *XXX.*

*XXX* is a type of cancer that occurs in the *XXX*. *XXX* is considered *[high risk (or low risk)]* when it *XXX.* The term, risk, refers to the chance of the cancer coming back after treatment*.*

This study is called a clinical trial. A clinical trial is a research study involving treatment of a disease in human patients.

It is common to enroll children and adolescents with cancer in a clinical trial that seeks to improve cancer treatment over time. Clinical trials include only people who choose to take part. You have a choice between a *standard* *[if there is no standard treatment replace with “another”]* treatment for *XXX* disease and this clinical trial.

*If applicable:*

*XXX* is a new type of drug for *XXX* [*disease site cancer].* Laboratory tests show that it may help slow the growth of *XXX [disease site cancer]. XXX* *has been shown to [add as appropriate, e.g., 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 *XXX* to treat this kind [*and/or stage]* of cancer *[in children]*, although *[add if applicable*: *they have* *approved its use in adults and]* they have allowed its use in this study. The research ethics board, which oversees the ethical conduct of research involving humans has reviewed and accepted this study.

Please take your time to make your decision. You may want to discuss it with your friends and family. We encourage parents/guardians to include their child in the discussion and decision to the extent that the child is able to understand and take part.

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.

**What is the current standard of treatment for this disease?**

*What is best known treatment to date and how was this established? (Briefly in 2 to 3 short sentences.) Note, this section should reflect standard or usual treatment.*

**Why is this study being done?**

*Per the PedCIRB letter dated 7/7/10, be careful with the use of “safe” when describing an experimental agent. The PedCIRB prefers the use of “well-tolerated” instead of “safe” in the following text: “Although [study drug] is investigational and has not been approved by the FDA, it has been shown to be ~~safe~~* ***well-tolerated*** *in children and adults.”*

*Include clear statements indicating the procedures that are experimental. For example for ACNS0423 this section should state "… This study looks at how well the combination of temozolomide and lomustine (CCNU) works when given to children [include “and young adults” if age range includes > 18] with high-grade gliomas after they receive radiation therapy and 42 days of temozolomide. The combination of temozolomide and lomustine after radiation is experimental."*

**The overall goal of this study is to**

*Identify goal and what is the research leading to this goal and how it is different from standard therapy.* *Bold the goal.*

*Try to use original NCI simple wording:*

* + **Phase 2 study** Find out what effects, good and/or bad, *[drug/intervention]* has on people with your *[specify type/stage/presentation of]* cancer.
  + **Phase 3 study** Compare the effects, good and/or bad, of *[drug/intervention]* with *[commonly-used drug/intervention]* on people with your *[specify type/stage/presentation of]* cancer to find out which is better. In this study, you will get either the *[drug/intervention*] or the *[commonly-used drug/intervention]*. You will not get both*.*

**What will happen on this study that is research?**

The treatment involves cancer fighting medicine called chemotherapy plus *XXX*. *[Modify as appropriate for study medications.]* The treatment on this study takes about *N* months. It is divided into *N* stages.

Most of the treatment in this study is standard or regular therapy for people with *XXX*. Treatment that is standard for *XXX* is described in **Attachment #1**.

Some parts of the treatment on this study are different from standard therapy. These parts are experimental and are…

*Describe the experimental portion(s).*

*If there are more than one treatment plan. Modify this wording as needed to reflect the study design. The “Summary…” heading may not always be necessary (e.g., if there is only 1 or 2 treatment plans).*

**Summary of Study Treatments**

In this study you will get 1 of *X* treatment plans. The *X* treatment plans are the same except for some differences during the *XX* and *XX* phases of therapy. The rest of the treatment that is given is standard therapy for people with *XX*.

*Expand the list as necessary.*

The *X* treatment plans are called Arm *X* and Arm *XX,* as follows:

* **Arm *X*:**
* **Arm *XX*:**

*If there is randomization:*

Random Assignment

You will receive 1 of *X* different treatment plans. The treatment plan that you receive is decided by a process called randomization. Randomization means that the treatment is assigned based on chance. It is a lot like flipping a coin, except that it is done by computer. You and your study doctor will not pick which treatment you get. The randomization process is described in the COG Family Handbook for Children with Cancer.

*If there are 2 treatment arms:*

Some participants will be randomized to receive treatment on Arm A; others will be randomized to receive treatment on Arm B.

*If there is more than 1 randomization:*

Here is how it will work:

Randomization Part #1: Some participants will be randomized to receive *XX*; others will get *XXX*. The rest of *XXXX* therapy will be the same in both groups of participants.

Randomization Part #2: In the *XX* phase, participants will be randomized to 1 of *X* treatments. In the first treatment, participants receive *XXX*. In the other treatment participants receive *XXXX*.

You will be told which treatment you are to get.

*Or*

This is a double-blind study, which means that neither you nor your study doctor will know which treatment you are receiving. Your experimental 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.

**Diagram of Treatment**

This chart shows the treatments on this study.

*Insert a simple layout of treatment, or append as appropriate*

**Treatment that is Research**

*Describe how the experimental therapies will be given; use tables to provide details of drug administration. (Tables are helpful to illustrate the comparisons when there is more than one treatment arm.) Use of supportive care drugs such as mesna: include administration details in the same location as the drug(s) requiring the supportive care drug (i.e., in these tables or in the attachment for standard therapy). Use the same rule for the location of risks.*

**Treatment for participants who are on Arm X**

|  |  |  |
| --- | --- | --- |
| **Drug** | **How the drug will be given** | **Days** |
|  | *If IV, include infusion time* |  |

*[If there are any special circumstances about the infusion, include them here. For instance, tolerance of bevacizumab and reduction of IV timing for second and subsequent infusions; or if an agent may be given by a route other than that listed above (IV instead of SubQ).]*

**Treatment for participants who are on Arm XX**

|  |  |  |
| --- | --- | --- |
| **Drug** | **How the drug will be given** | **Days** |
|  | *If IV, include infusion time* |  |

*Describe the procedures that are used in the study, including clear identification of those procedures that are experimental.*

**Non-Experimental Research Study Tests and Procedures**

*For all studies:*

*Do not repeat biology studies that are a separate study (i.e., disease biology/tumor banking study such as AALL03B1). Explain tests briefly and simply. For required tests, state if taking extra tissue (e.g., blood) at the time of a regular test or if participating will mean extra procedures (e.g., extra needle sticks). Also inform if test results will be given back to patient and if treatment decisions will be made based upon the results.* *It is not necessary to describe the risk associated with blood draws, or other tests or procedures with which the participant population would already be familiar. However, "amounts" of blood and schedule/number of blood draws and tests need to be included in this section.*

The following tests will be done because you are part of this study. If you were not in the study you would probably not have these tests.

*List required tests/procedures that are only being done due to participation in the study, e.g., MRD in an ALL trial. In a trial that includes both required and optional tests, optional tests should be included in a separate optional consent form.*

*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.

*If applicable*:

Hepatitis Testing

This study involves testing to determine your Hepatitis xx status. This test is required for this research study to find out if [provide the reason for the test if not described elsewhere in the consent - e.g., you meet the eligibility requirements, etc.]

 If you test positive for Hepatitis xx, you [will not/will] be able to participate in this study.

If you test positive for Hepatitis xx your doctor will be required to share your identity and the results of your test(s) with Public Health.

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

*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*

Some study-specific procedures/tests and activities may take place closer to your home or at another location. Your study doctor will discuss this information with you, if this is a possibility.

**Experimental Research Study Tests and Procedures**

*Only include if there are experimental tests that are being tested as part of this study. Any standard procedures (e.g., MRI, blood draw, etc.) that are done or done more frequently as part of the study should be included in the ‘non-experimental procedures’ section – this section is for procedures that are experimental (e.g., being tested as part of the research, such as unapproved use of PET scan; unvalidated biomarker assay). 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:

*If applicable:*

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

*List the procedures and tests. Include explanation of what each test involves and the purpose/reason/rationale for including it in the research*

*If applicable:*

**Questionnaires**You will be provided with a questionnaire before starting this study, and then every [*describe: e.g. 3 months while you are receiving treatment and once a year after treatment up to 5 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 can choose not to answer these if you wish.

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

*If participant diaries are protocol-mandatory, 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.

**Central (*specify type of review: e.g., Radiology, Radiotherapy, surgical*) Review**

*If applicable: Adapt and insert the following sentence if there is central review of tissue and/or scans without the results being used to make treatment decisions.*

Some of the tissue already taken and copies of the scans used to diagnose the cancer will be sent to a central review center as part of COG quality control.

*If applicable:*

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 conducting 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 sampls(s). If he sponsor requires the participant’s initials to be part of the participant’s study code, add]* which may include your initials]. *Identifiers such as "patient or hospital identification number" may not be used*.

*If applicable:*

**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 may only 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 may only 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).*

Tests need to be completed on your samples (described below) to make sure you have the type of cancer that is being studied in this research study *and/or* to see how the cancer cells respond to the *XXX [name of study drug]*. *[Study-specific explanation of the research purposes should be provided here.*

*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.

Certain types of genetic testing could have implications for your biological relatives or affect your insurability. Please ask your study doctor whether this might apply to you as a result of your participation in this study.

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.

*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 applicable*

**Tissue Collection**

*If applicable:*

*If an archival sample is 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.*

*OR*

*If applicable:*

*If a fresh 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 sized piece]* of your *XXX [type of cancer]*. *Explain in lay language whether this would be done using a local or general anesthetic and whether overnight hospital stay would 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 note: minimum required location is Country],* where they will be examined to confirm your diagnosis *[or explain the purpose]*.

*If applicable*

**Blood/Urine Collection**

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 note: 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 note: 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)]. If the sponsor requires the participant’s initials to be part of the study code, add,] which may include your initials.*

Withdrawal of Required Samples

If you no longer want your samples to be used in this research, tell your study doctor. Your study doctor will notify the sponsor who will ensure that 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.

*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 for Research**

*Provide a brief description of the optional tests. The details should be included in a separate optional consent form*

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.

**What are my 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 in another research study.
* Return any unused study medication.
* Return any diaries or questionnaires that were completed at home 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]*

*[Specific drug interactions that pertain to a specific XXX (agent) should be identified within the agent’s risk section.]*

**What side effects or risks can I expect from being in the study?**

**Treatment Risks**

**All people who receive cancer treatment are at risk of having side effects. In addition to killing tumor cells, cancer chemotherapy can damage normal tissue and produce side effects. Side effects usually get better when the medication is stopped but sometimes they last a long time or never go away. Some side effects are not very dangerous, but some can be life-threatening or cause death.**

*If appropriate:*

The risks of the individual drugs given as standard treatment and risks of radiation therapy are listed in **Attachment #2**.

**Common side effects include nausea, vomiting, hair loss, and fatigue (tiredness). Drugs may be given to try to prevent or decrease nausea and vomiting. Hair loss is usually temporary but very rarely it may be permanent. Some chemotherapy may make people permanently unable to have children. On rare occasions, people can get a second cancer from chemotherapy. This usually happens years after the chemotherapy is finished.**

**Side effects can be increased when chemotherapy drugs are combined.**

**The most common serious side effect from cancer treatment is lowering of the number of blood cells resulting in anemia, increased chance of infection, and bleeding tendency**.

Low blood counts and how to care for someone with low blood counts are described in the COG Family Handbook for Children with Cancer.

**Risks of Study**

The use of *XXX* instead of *XXXX* may cause more complications.

The *XXX* treatment that is being studied could be less effective than the current standard treatment.

*Insert risks for the experimental therapy (e.g., drug tables, RT risks).*

*Note: may use NCI US template for risk categorization or a recognized alternative (e.g., CIOMS)*

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

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

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

In addition to the risks described above, there may be unknown risks, or risks that were not anticipated, associated with being in this study.

*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 *[#]* people have been given this drug and the side effects that have been reported are: *[specify - examples]*

* *<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 [*name of drug]* 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 if applicable:*

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 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 and 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.

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

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

**Reproductive risks**

The effects that XXX may have on an unborn baby (fetus) are unknown.

**Women should not become pregnant and men should not father a baby while on this study because the drug(s) in this study can be bad for an unborn baby. If you or your partner can get pregnant, it is important for you to use methods to prevent pregnancy or not have sex while on this study. Check with your study doctor about what kind of methods to use and how long to use them. Some methods might not be approved for use in this study. Women should not breastfeed a baby while on this study. Also check with your study doctor about how long you should not breastfeed after you stop the study treatment(s).**

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

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

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

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 you become pregnant, the researchers or sponsors for this study will access information on the outcome of the pregnancy (the child’s health etc.). This information will be gathered from your medical/study record. This may also involve contacting you *[specify duration]* for the next *[specify duration]* years to ask about the health of your child. The researchers or sponsor may also ask to contact the child’s father to get information related to the pregnancy. If you become pregnant and do not want the researchers/sponsors to collect this information, you must let your study doctor know.

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 health, etc.). Your partner will be given a separate consent document to sign to give permission for the collection of this information, if a pregnancy should happen. Your partner 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 on the study and will not result in any penalty or any loss of benefits to which you are entitled.

*Note: 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.

**Are there benefits to taking part in the study?**

If you agree to take part in this study, the experimental treatment may or may not be of direct benefit to you.

Potential benefits to you could include: *[Select potential benefits from list.]*

* getting rid of your cancer for a long time or for the rest of your life, (*This may not be appropriate for some studies, e.g., Phase 2 (especially DVL). Request input from study chair.)*
* your cancer is controlled for a longer period of time,
* fewer side effects,
* a shorter time to be treated successfully,
* fewer long term side effects (for example, being less likely to develop problems with the heart, lungs, kidneys; being less likely to have learning problems, or, less risk of getting another cancer later as a result of treatment).

With any cancer treatment, sometimes treatment does not make the cancer go away. Or, sometimes treatment makes the cancer stay the same or go away for a while but the cancer comes back later.

We hope that the information learned from this study will help other patients in the future.

**What other options are there?**

You do not have to take part in this study in order to receive treatment/care. Instead of being in this study, you have these options:

* **Current standard therapy even if you do not take part in a study. Standard therapy is described on page 1. It is Arm *X* of this study.** *If there is no standard treatment, replace this bullet with the following bullet:*
* ***Getting treatment for your cancer without being in a study.***
* **Taking part in another study.**

*For relapsed studies where there is no standard of care (****check with STUDY CHAIR before inserting****)*

* ***Getting comfort care, also called palliative care.*** *This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly. Instead it tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.*

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

**How many people will take part in the study?**

The total number of people enrolled on this study is expected to be *XX*. *[If this is a multi-phase study, indicate how many on each phase.]*

*ALL Phases example:*

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

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

**How long is the study?**

Participants in this clinical trial are expected to receive treatment on this study for about *X* years. After treatment, you will have follow-up examinations and medical tests.

*Check the requirements for follow-up if this is a non-treatment study*

We would like to continue to find out about your health every year for about *X* *[10 for most phase III studies, 5 for most phase II studies (exceptions must be approved by the study statistician)]* years after you enter this study. By keeping in touch with you for a while after you complete treatment, we can better understand the long-term effects of the study treatments.

You can stop taking part in the study at any time. However, if you decide to stop participating in the study, please talk to the study doctor and your regular doctor first. They will help you stop safely.

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.
* A Regulatory authority such as Health Canada, or the Research Ethics Board withdraws permission for the study to continue.
* Your treatment assignment becomes known to you or your study doctor. *(include this statement only If applicable)*
* If you become pregnant *(include this statement only If applicable)*

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

**What about privacy?**

***Note:*** *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 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.

If you receive care in a satellite hospital, your (personal health information) identifiable information, including lab values and physical findings may also be collected.

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.

The Children’s Oncology Group has received a Certificate of Confidentiality from the federal government, which will help us protect the privacy of our research participants. Information about the certificate is included in **Attachment #3**.

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:*

* **Children's Oncology Group**
* **Representatives of the National Cancer Institute (NCI), Food and Drug Administration (FDA), and other U.S. *[and international governmental]* regulatory agencies involved in overseeing research**
* *Health Canada (because they oversee the use of drugs in Canada)* *(include this statement If CTA has been submitted to Health Canada)*
* **The Ontario Cancer Research Ethics Board, which oversees the ethical conduct of this study at your hospital/clinic**
* **The drug company that makes the drug, *XXX,* or their designated reviewers*.*** *(Include if an industry sponsored trial. Per CTEP, do not name the drug company. This will avoid updates due to changes in specific company designations).*
* *LIST other 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, initials, sex, date of birth.]*

*Delete any example below that does not apply, or list additional organizations:*

* **Pediatric Central Institutional Review Board (CIRB) of the National Cancer Institute *(****Include if appropriate.)*
* *Other regulatory authorities (because they oversee the use of drugs in other countries) (if applicable) (list)*
* Central laboratories or central review centres *(e.g., for trials with tissue collection for the confirmation of diagnosis, radiological review etc.)*

All of the organizations listed in the above 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*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.

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

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 is 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 studies. If your study data is shared with other researchers, information that links your study data directly to you will not be shared.

You should be aware that privacy protections may differ in other countries.

**What are the costs?**

*Include if agent is supplied for free:*

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

* You stop participating on 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 as what will happen if there is no more drug available.

*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 if not applicable*

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 *[study 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). You may have to pay for medication prescribed to treat or prevent side effects, and you may have to visit the hospital/clinic more often than if you were not participating in this study.

*If applicable, inform the patient of any tests or procedures for which there is no charge. Indicate if the patient and/or health plan is likely to be billed for any charges associated with these ‘free’ tests or procedures.*

*Include the following section if a study agent is* ***manufactured by a drug company and provided by the NCI at no charge****.*

The NCI will supply the *[study 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 *[study agent(s)]* to the NCIfor some reason. If this does happen, other possible options are:

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

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

*Include the following section if a study agent is* ***manufactured by the NCI******and provided at no charge****.*

The NCI will provide the *[study agent(s)]* at no charge while you take part in this study.

Even though it probably won’t happen, it is possible that the NCI may not be able to continue to provide the *[study agent(s)]* for some reason. If this does happen, the study may have to close. Your study doctor will talk with you about this, if it happens.

*Include the following section if a study agent is being* ***provided directly by a drug company at no charge****.*

The drug company that makes *{Insert the name of the agent}* is supplying the drug at no charge for this study.

**Compensation**

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

*Include the following if applicable*

* “You will be reimbursed for study-related expenses such as parking etc.”

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 side effects or injury, medical care will be provided by your study doctor or you will be referred for appropriate medical care.

You do not give up any of your legal rights for compensation by signing this form. This consent form does not relieve the investigator, the hospital, the sponsor, and their agents from their legal and professional responsibilities.

**Conflict of Interest** **/Funding Support**

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

If you choose to enroll on this study, this institution will receive some money from the Children’s Oncology Group to do the research.

*Insert for industry sponsored or funded trials*

The drug company that makes *{Insert the name of the agent}* is providing money to the Children’s Oncology Group to do the research.

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 the Office of the Chair of the Ontario Cancer Research Ethics Board. (contact information below)

**What are my rights as a participant?**

Taking part in this study is voluntary. You may choose not to be in this study. If you decide not to be in this study, you will not be penalized and you will not lose any benefits to which you are entitled. You will still receive medical care.

You can decide to stop being in the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study, your doctor will discuss other options with you and continue to treat you with the best means available.

Your study doctor will tell you about new information that may affect your health, welfare, or willingness to stay in this study. A committee outside of COG closely monitors study reports and notifies COG if changes must be made to the study. Members of COG meet twice a year to discuss results of treatment and to plan new treatments.

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.

*If the study is a treatment study:*

During your follow-up visits after treatment, you may ask to be given a summary of the study results, which will only be available after the study is fully completed*. A summary of the study results will also be posted on the Children’s Oncology Group website (http://www.childrensoncologygroup.org/).* To receive the results, you may either (1) go to the COG website to check if results are available or (2) register your information with the COG on its web site and have an email sent to you when the results are available. Your pediatric oncology team from your hospital can give you additional instructions on how to do this. Please note, that the summary of results may not be available until several years after treatment for all people on the study is completed, and not only when you complete treatment.

*If the study is not a treatment study, e.g. biology/classification study, replace the above paragraph as follows:*

During your follow-up visits, you may ask to be given a summary of the study results, which will only be available after the study is fully completed*. A summary of the study results will also be posted on the Children’s Oncology Group website (http://www.childrensoncologygroup.org/).* To receive the results, you may either (1) go to the COG website to check if results are available or (2) register your information with the COG on its web site and have an email sent to you when the results are available. Your pediatric oncology team from your hospital can give you additional instructions on how to do this. Please note, that the summary of results may not be available until several years after the study is completed, and not only when you complete participation on this study.

**Whom do I call if I have questions or problems?**

For questions about the study or if you have a research related problem or if you think you have been injured in this study, you may contact your study doctor. Or you can meet with the doctor who is in charge of the study at this institution/centre. That person is:

|  |  |  |
| --- | --- | --- |
|  |  |  |
| 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 Office of the Chair of the Ontario Cancer Research Ethics Board at:

|  |  |  |
| --- | --- | --- |
| Telephone: 416-673-6648 |  | Toll Free: 1-866-678-6427 ext. 6648 |

**Where can I get more information?**

TheCOG Family Handbook for Children with Cancerhas information about specific cancers, tests, treatment side effects and their management, adjusting to cancer, and resources. Your study doctor can get you this Handbook, or you can get it at <http://www.childrensoncologygroup.org/familyhandbook>.

Visit the NCI's Web site at <http://www.cancer.gov>.

For more information on clinical trials you can visit the National Cancer Institute’s Web site at <http://www.cancer.gov/clinicaltrials/learningabout>.

Information about long term follow-up after cancer treatment can be found at: <http://www.survivorshipguidelines.org/>.

*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.

*All other trials, replace the above paragraph with:*

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

You will get a copy of this form. You may also ask for a copy of the protocol (full study plan).

**Signature**

**I have been given a copy of all \_\_\_\_\_ pages of this form. The form includes *[number xx, e.g., three (3); insert appropriate number]* attachments.**

* All of my questions have been answered,
* I understand the information within this informed consent form,
* I allow access to my medical records and specimens as explained in 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,
* I do not give up any of my legal rights by signing this consent form,
* I agree to take part in this study.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Signature of Participant |  | PRINTED NAME |  | Date |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Signature of Person Conducting the Consent Discussion |  | PRINTED NAME |  | Date |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| 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 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 |

**Attachment #1**

**Treatment and Procedures Common to all Patients with *XXXX***

**Methods for Giving Drugs**

Various methods will be used to give drugs:

* **PO** - Drug is given by tablet or liquid swallowed through the mouth.
* **IV** - Drug is given using a needle or tubing inserted into a vein. Drugs can be given rapidly over a few minutes (“push”) or slowly over minutes or hours (“infusion”).
* **IM** - Drug is given into a muscle using a needle.
* **SubQ** - Drug is given by inserting a needle just under the skin.
* **IT** - Drug used to treat the brain and spinal cord is given using a needle inserted through the back into the fluid surrounding the spinal cord.

**Central Line**

Your doctor may recommend that you get a special kind of IV called a “central line.” This is a kind of IV placed into a big vein in your chest that can stay in for a long time. The risks connected with central lines will be explained to you and all of your questions will be answered. If you are to have a central line inserted, you will be given a separate informed consent document to read and sign for this procedure. A description of the types of central lines is in the COG Family Handbook for Children with Cancer.

**Standard Treatment Tables**

The treatment described below is standard treatment for patients with *XXX*.

*Insert a description of the standard therapy for each relevant treatment phase. If there is more than one treatment arm, state whether this therapy applies to all patients or to those on a specific arm.*

|  |  |  |
| --- | --- | --- |
| **Drug** | **How the drug will be given** | **Days** |
|  | *If IV, include infusion time* |  |
|  |  |  |
|  |  |  |
|  |  |  |

**Standard Tests and Procedures**

The following tests and procedures are part of regular cancer care and may be done even if you do not join the study.*[include the following examples as appropriate]*

* Frequent labs to monitor your blood counts and blood chemistries. *[if the study arm is observation only, confirm if this statement applies]*
* Urine tests to measure how your kidneys are functioning.
* Pregnancy test for females of childbearing age before treatment begins.
* X-rays and scans to monitor your response to treatment.
* Tests to monitor your heart and lung function.
* Bone Marrow Aspirations to see if the cancer is responding to treatment. The bone marrow procedure is described in the COG Family Handbook for Children with Cancer.
* Spinal Taps to check for cancer cells in the spinal fluid and to give chemotherapy into the spinal fluid. This is described in the COG Family Handbook for Children with Cancer.

**Attachment #2**

**Risks of Chemotherapy Drugs and Radiation Used to Treat *XXX***

**Risks and side effects related to Drug Name include those which are:**

|  |  |  |
| --- | --- | --- |
| **Likely** | **Less Likely** | **Rare but Serious** |
|  | * **Fewer white blood cells, red blood cells and platelets in the blood.**   + **A low number of red blood cells can make you feel tired and weak** * **A low number of white blood cells can make it easier to get infections** * **a low number of platelets causes you to bruise and bleed more easily** |  |

***[Include risks of radiation therapy if standard care includes radiation therapy.]***

**Attachment #3**

**Certificate of Confidentiality**

The Children’s Oncology Group has received a Certificate of Confidentiality from the United States federal government, which ensures the protection of information provided by research participants when research data is held in the United States.  For Canadian participants whose data is sent to the U.S., the Certificate of Confidentiality ensures that their data are provided the same protections, once released into the U.S., as data obtained from U.S. participants which is retained in the U.S.

The Certificate of Confidentiality describes the measures that are used to protect your personal health information once, or if, it is released to the U.S. The federal government to which the statement below refers, is the U.S. government, not the Canadian government.

Information about the certificate is included below.

The Children's Oncology Group has received a Certificate of Confidentiality from the federal government, which will help us protect the privacy of our research participants. The Certificate protects against the involuntary release of information about participants collected during the course of our covered studies. The researchers involved in the studies cannot be forced to disclose the identity or any information collected in the study in any legal proceedings at the federal, state, or local level, regardless of whether they are criminal, administrative, or legislative proceedings. However, the participant or the researcher may choose to voluntarily disclose the protected information under certain circumstances. For example, if the participant or his/her guardian requests the release of information in writing, the Certificate does not protect against that voluntary disclosure. Furthermore, federal agencies may review our records under limited circumstances, such as a DHHS request for information for an audit or program evaluation or an FDA request under the Food, Drug and Cosmetics Act.

The Certificate of Confidentiality will not protect against the required reporting by hospital staff of information on suspected child abuse, reportable communicable diseases, and/or possible threat of harm to self or others.