

**If the study includes genetic analyses of blood or tissue, or if the study requests permission to store blood or tissue for future research, see suggested language for genetic studies.**

<http://www.ohsu.edu/ra/forms.shtml#hsf>

**FOR INITIAL OR ANNUAL REVIEW, PLEASE LEAVE THE “APPROVED:” DATE BLANK AS THIS SHOULD BE COMPLETED MANUALLY AFTER YOU HAVE RECEIVED THE STAMPED APPROVED CONSENT FORM FROM THE IRB.**

**IRB#** \_\_\_\_\_

**Protocol Approval Date:** [Insert initial approval date or most recent annual approval date]

**OREGON HEALTH & SCIENCE UNIVERSITY  
OHSU Cancer Institute Consent Form Sample for COG Studies**

**SUBJECT NAME:** \_\_\_\_\_ **DATE:** \_\_\_\_\_

**TITLE:** COG# *Name of the study. Use the same title as that on the IRQ*

**PRINCIPAL INVESTIGATOR:** [list name and degree(s)] (503) 494-####

**CO-INVESTIGATORS:** [list name and degree(s)] (503) 494-####  
[list name and degree(s)] (503) 494-####  
[list name and degree(s)] (503) 494-####

Investigators should be same as those listed on the IRQ. Everyone involved in the study, including research nurses and research assistants, should be listed here.

**SPONSOR:** National Cancer Institute/Children’s Oncology Group (COG)

**INTRODUCTION:**

“You” refers to you or your child in this consent form. You have been invited to participate in this research study because \_\_\_\_\_.

This is a clinical trial (a type of research study). Clinical trials include only patients who choose

to take part. Please take your time to make your decision. Discuss it with your friends and family.

### **WHY IS THIS STUDY BEING DONE?**

*Here are some example purpose statements. Choose the ONE most applicable to your study. Modify the statements as necessary if you are using a device or treatment technique such as surgery or radiation or a biological product (donor or autologous bone marrow) instead of a drug.*

**Phase I studies:** The purpose of this study is to test the safety of the study drug XXX to see what effects (good and bad) it has on you and your type of cancer.

OR

Find the highest dose of the study drug XXXX that can be given without causing severe side effects.

**Phase II studies:** Find out what effects (good and bad) the study drug XXXX has on you and your type of cancer.

**Phase III studies:** Compare the effects (good and bad) of XXXX and XXXX on you and your type of cancer. We do not know which of these two treatments is better.

**Other:** This research is being done because XXX. *[Explain in one or two sentences.]*

*For studies involving storage of blood or tissue samples use the following language. If studies may involve genetic analyses, this must be stated:)* We are also asking you to allow us to use some of your blood or issue for future [genetic] research as part of the search for the cause of cancer. Genes are the units of DNA--the chemical structure carrying your genetic information--that determine many human characteristics such as the color of your eyes, your height, and whether you are male or female. The blood/tissue samples you give us will be used to see whether there are differences in the genes of people with and without cancer. Your blood [or tissue] will be preserved as long as possible.

*(COG Required Language):* As part of the ongoing scientific and biotechnical activities of the Children's Oncology Group, and its agents, if you agree, these tissue specimens may be preserved indefinitely and used for future research purposes. This is called a blood or a tissue bank.

### **HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**

*If appropriate, state:* As many as XXX people will take part in this study which will be

conducted at [*Oregon Health & Science University and/or other hospitals and Universities nationally*]. Of these patients, up to XXX will be enrolled at OHSU.

### **WHAT IS INVOLVED IN THIS STUDY?**

1. *If there will be a placebo arm in the study, use the following statement:* A placebo is a pill or solution that tastes, looks, and smells like the study drug but has no real medicine in it. A placebo is sometimes called a “sugar pill.”
2. *Indicate how patients are assigned to different treatments or conditions. Sample language (modify as appropriate to fit your study):* This is a randomized study. . This means that you will be selected to get either the active drug or the placebo by chance like tossing a coin). Neither you nor your doctor can choose whether you get the active drug or the placebo. You have a [*insert proportion*] chance of getting the active drug in this study.
3. *Indicate whether patients or doctors will know what treatment patients are receiving (single/double-blind); sample language (modify as appropriate to fit your study):* You and the study doctors/nurses will not know whether you are getting the drug or the placebo. The study is done this way because knowing whether you are taking the placebo or the study drug can change the results of the study. If you have serious side effects or other problems, the study doctors can find out whether you are taking the study drug or not if it is needed for your safety and well-being. Please ask the study doctor for more information on placebos or randomized studies if you have any questions about this kind of study.
4. *Describe succinctly and in chronological order those procedures that are part of the research. It is not necessary to describe procedures that are part of routine care. State approximately how much time visits and procedures will require. If studies are complex, provide a table showing what procedures will occur at each study visit (see example table below). Here is an example statement from one study:* The study will involve chemotherapy treatment for all patients and radiation for patients who have symptoms from their brain metastases. Radiation will be given for 10 treatments (daily Monday through Friday) and will be started at the same time as chemotherapy. Chemotherapy will consist of a 30-minute injection of topotecan every day for 5 days. This treatment will be repeated in 3 weeks and then x-rays and blood tests will be done to see if the cancer is shrinking. If so, chemotherapy will begin with two different chemotherapy drugs: cisplatin (given by vein on day 1) and etoposide (given by vein on days 1-3). The cisplatin and etoposide treatment will alternate with the topotecan treatment so that a course of chemotherapy will be given every three weeks for a maximum of eight treatment cycles. X-rays and bloods tests to see if the cancer is responding to treatment will be repeated every two cycles (6 weeks). All the tests that you will have are part of regular cancer care and may be done even if you do not join the study.

Regimen 1	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6-10
Radiation	X	X	X	X	X	X
Topotecan	X	X	X	X	X	
Total time	2 hours	2 hours	2 hours	2 hours		1 hour

Alternates with

Regimen 2	Day 1	Day 2	Day 3
Cisplatinium	X		
Etoposide	X	X	X
Total time	2 hours	2 hours	1 hour

5. *If blood is to be drawn, indicate the amount in lay terminology (4cc = 1 teaspoon, 15cc = 1 tablespoon, etc).*
6. *If radiation is part of the experimental study, Radiation Safety Committee review of your protocol is required. Contact the Radiation Safety Officer (4-7795; francoj@ohsu.edu) for advice and documents. Please note that all studies using DEXA scans need to be submitted to Radiation Safety for review.*
7. *If a questionnaire is being used, mention what kinds of questions are being asked, indicate how long it will take to do the questionnaire, and submit a copy of the questionnaire to the IRB along with your protocol and consent form.*
8. *For studies involving the collection and storage of blood or tissue, including genetic studies, you must indicate what will be collected, how it will be collected, how long it will be stored, and whether any identifiers will be retained with the sample. (Sample Language): If you agree, a blood/tissue sample [state amount] will be taken [when; how]. This sample will be stored for future research. Tumor tissue left over from previous surgeries or biopsies will also be stored. The samples will be labeled as described in the CONFIDENTIALITY section. We will also ask you to sign a release that will allow us to review your medical records. You may be asked to give us health information about your relatives. Any information you give us will be kept confidential. We will not contact your relatives without their permission. We may discuss with you the possibility of including your relatives in the study in the future.*

## **SUBJECT ACCESS TO GENETIC INFORMATION**

*(OHSU Required Language):* We will not give you or your family members the results of any genetic test, now or in the future. This is because we do not know whether the results are reliable and the results will not be helpful for your treatment.

### **HOW LONG WILL I BE IN THE STUDY?**

1. *Sample Language:* You will be in the treatment phase of the study for up to [give duration]. Once the study treatment is finished, you will be followed to see whether your cancer recurs and to look for any side effects of the treatment. However, the researcher may take you off this study if your cancer does not improve, if any new areas of cancer develop, if you become pregnant, if you have serious side effects, if you fail to follow instructions, or if your doctor determines that it is in your best interest. You can drop out of the study at any time. However, if you decide to drop out of the study, we encourage you to talk to the researcher and your regular doctor first to be sure that the study is stopped in a way that will be safe and comfortable for you.
2. *State that the subject will be informed of any new findings that may affect the subject's willingness to continue to participate. Sample language:* You will be told if we learn anything in doing this study that might make you want to change your mind about continuing to be in the study.
3. *Indicate what procedures, if any, the subject will be asked to complete if the subject chooses to withdraw. If the protocol involves bone marrow transplantation, subjects should be warned that stopping the protocol at some stages will result in death.*

### **WHAT ARE THE RISKS OF THE STUDY?**

1. *Describe reasonably foreseeable risks, side effects, discomforts, or inconveniences. Sample language:* While on the study, you are at risk for the following side effects. You should discuss these with the researcher and/or your regular doctor. There also may be other side effects that we cannot predict. Other drugs will be given to make side effects less serious and uncomfortable. Many side effects go away shortly after the chemotherapy or radiation are stopped, but in some cases side effects can be serious or long lasting or permanent.
2. *Examples of typical chemotherapy/radiation side effects:* Suppression of the white blood cells (infection fighting cells) which can lead to susceptibility to infection that can be life threatening; suppression of the platelet count which can cause bleeding and may require blood transfusions; hair loss which may be complete; nausea or vomiting which may be severe but are generally well controlled with anti-nausea medication; skin reaction like a mild to moderate sunburn in patients receiving radiation; fatigue; altered taste; loss of appetite; numbness or tingling in the fingers and toes.

3. *Indicate risk of inducing a secondary malignancy, if pertinent.*

4. *Use standard wording where applicable:*

***For venipuncture:*** You may feel some pain when your blood is drawn. There is a small chance the needle will cause bleeding, a bruise, or an infection.

***For x-rays, DEXA scans, and nuclear medicine procedures:*** In this study you will be exposed to radiation during the [name of the procedure ]. While we can't be sure any dose of radiation is entirely safe, the amount you'll be exposed to in this study is not known to cause health problems.

***For CT scans:*** In this study, you will be exposed to radiation during the CT scan. Although the dose to which you will be exposed is higher than from a typical x-ray, the risk of harmful effects from a single exam is very small.

***For fluoroscopy:*** In this study you will be exposed to radiation during the fluoroscopy for [name of the procedure]. There is a small chance this will cause you to lose your hair. Your skin may be damaged or turn red. If these rare side effects occur and do not get better on their own, you may need medical treatment.

***For indwelling catheter:*** You will have a catheter (tube) in your vein for more than 24 hours. You may get an infection where the tube is placed. This would cause swelling, redness and pain. You may bleed or get a bruise. There is a small chance your blood stream or heart valves might get a serious infection. You may get a blood clot that could go to your lungs. These problems are very rare. If you have these problems, you will need hospital care. Your tube will be in place for (state time).

***For protocols involving surgery that is NOT investigational:*** You are invited to be in this research study because you are scheduled to have (name procedure). You have already consented to that procedure. That procedure is not experimental and is not part of this study. The risks of (name procedure) have already been discussed with you and a copy of that consent form is attached to this research consent form. Those risks include: (list briefly). ***NOTE: PI must provide provide a description of the significant material risks of the procedure in a separate clinical consent form and attach a copy of the clinical consent form to the research consent form.***

***For platinum based drugs:*** *Include the possibility of total, permanent hearing loss.*

***For studies using carboplatin, etoposide phosphate or cytoxan:*** With the administration of carboplatin, etoposide phosphate or cytoxan, there is an increased risk of pre-leukemia which is usually fatal. The chance of this complication occurring is not known at this

time but appears to be small.

***For COX-2 inhibitors or similar compounds:*** Some researchers believe COX-2 inhibitor type drugs might increase the risk of heart attack, stroke, angina (chest pain), blood clots, and death. We're not sure this is true but we want to be careful. To help keep you safe in this study, we will closely watch you for these side effects by [*describe monitoring plan here*].

***For studies using epoetin alfa:*** In subjects with chronic kidney disease who have received months to years of treatment with another brand of epoetin alfa, there have been reports of failure in production of red blood cells in the bone marrow, this is a type of anemia due to destruction of the cells that produced the red cells. Although there have been reports of this condition with the use of other recombinant erythropoietin products (like epoetin alfa), most cases occurred with a specific brand called EPREX.

Low numbers of RBC's (anemia) can cause fatigue and shortness of breath; these symptoms are treated with blood transfusions. About half of subjects with this type of anemia improve with or without treatment, but it is unknown how long the anemia will last. subjects with this type of anemia may need life-long transfusion therapy due to their lack of ability to make their own red cells.

***For studies using gleevec: include this with rare, but serious events:*** decrease or loss of vision, which can be permanent.

***For endoscopy:*** The endoscopy may make you gag. It may make you feel queasy or give you a sore throat. There is a small chance your esophagus, stomach, or small intestine may bleed. You may get an infection. Once in a great while, an endoscopy makes a hole in someone's esophagus or stomach. This happens about 1 time in every 5,000 endoscopies. If this happens to you, you may need to have surgery to repair the hole. You may feel drowsy after taking the drug that relaxes you before the endoscopy. You should not drive a car or operate machinery for 24 hours afterward.

***For bone marrow biopsy:*** Bone marrow biopsy means taking some cells from inside your bones. To do this, we will numb an area of your skin with a shot. Then we will insert a long needle into your bone to get the cells. The shot may cause a little pain. You may also feel a great pain when the cells are drawn in through the long needle. Your hip may hurt for about 3-6 days. There is a small chance you will get a bruise or an infection where the needle will be inserted. You may bleed or have a scar. Your skin may itch. These problems are rare.

***For other biopsy (skin, muscle, fat, etc):*** Biopsy means removing a small piece of tissue from (location). We will give you a shot to numb the area.. Some people (fewer than 1 in 10,000) are allergic to this kind of shot. Then we will make an incision (a cut) to take out

the tissue. Heavy bleeding from \_\_\_\_\_ biopsy is rare. Biopsies cause infections about 10% of the time. A small scar will form at the biopsy site. The scar is usually much smaller than the original cut. Sometimes it is almost invisible.

***For pregnancy/risk to fetus (For Women):*** We do not know how this (drug, treatment, procedure) could affect a fetus. If you are sexually active and at risk of getting pregnant, you and your male partner(s) must use a method [two methods] of birth control that work[s] well, like birth control pills, depo-provera, Norplant, an IUD, a diaphragm or condom with spermicide, or abstinence. You will have to do this the whole time you are in this study. If you become pregnant during the research study, please tell the investigator and your doctor immediately.

***For pregnancy/risk to fetus (For Men):*** If you are a sexually active male and can cause a pregnancy, you must be sure that your female sexual partner(s) are using a method of birth control that works well, like birth control pills, depo-provera, Norplant, an IUD, or a diaphragm with spermicide, or you must use a condom with spermicide during sexual intercourse. If you have had a vasectomy, this [is/is not] an acceptable method of birth control. You must do this the whole time you are in this study. If a sexual partner becomes pregnant during the research study, please tell the investigator and your doctor immediately.

***For studies that enroll identified HIV positive subjects:*** As an HIV positive person you can give the HIV virus to your sexual partner even if your viral load is very low or non-detectable. You must be sure that your sexual partner knows your status. If you use a condom or female condom during intercourse, you will help reduce the risk of giving your partner HIV. Using a spermicide (like nonoxynol 9) may increase the risk of giving HIV to your partner. The investigator will discuss with you ways to minimize this risk.

***For potential drug interactions:*** *Whenever a study involves the administration of medications that may interact with several other medications, the following statement (or its equivalent) must be included:* There are several drugs (prescription and non-prescription) that may cause problems when taken with the study drug. The investigator will carefully review all of the drugs you are taking before giving you the study drug. If any other health care provider prescribes any new drug(s) for you while you are in this study, please tell the investigator before you take the new drug. You could also have that provider talk to the investigator before prescribing the new drug. Do not take any new over-the-counter drugs while you are in this study unless you first check with the investigator.

***For studies involving interviews/questionnaires/QOL assessments that discuss sensitive issues, such as grieving:*** *The risk of emotional upset must be described, and subjects must be informed that they may refuse to answer questions that upset them. For example:* Some of these questions may seem very personal or embarrassing. They may upset you.

You may refuse to answer any of the questions that you do not wish to answer. If the questions make you very upset, we will help you to find a counselor.

### **ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**

1. If you agree to take part in this study, there may or may not be direct medical benefit to you. We hope the information learned from this study will benefit other patients with XXX cancer in the future.
2. *[For Phase 3 studies, when appropriate:]* The possible benefits of taking part in the study are the same as receiving *[standard treatment or intervention]* without being in the study.

### **WHAT OTHER OPTIONS ARE THERE?**

1. You may choose not to participate in this study.

*If the study involves collection and storage of blood or tissue, but genetic or other studies of the blood or tissue are not necessary for determining eligibility or assigning the study treatment, participation in the storage of blood or tissue must be optional. Use the following OHSU, required statement: You may choose not to take part in this study at all, or you may choose to take part in the experimental treatment without participating in future [genetic] research.*

2. Instead of being in the study, you have these options: *[List alternatives including commonly-used therapy]*
3. If you decide that you do not want any further active treatment for your *<insert disease or condition>*, one of your options is called “comfort care.” Comfort care means that your doctor will offer you medication to help control your pain, together with any other treatment and support you need to help you maintain your overall comfort and dignity. It is often possible for this comfort care to be provided at home.

If you think that comfort care is something you might prefer, feel free to discuss it with family and friends, any spiritual advisor, and of course, your doctor.

4. *[If appropriate (for noninvestigational treatments):]* You may get the same treatment being offered in this study even if you do not take part in the study. You can also choose to receive comfort care (care to help control pain and other symptoms) only.
5. Please talk to your regular doctor about these and other options. *[Reference and attach any information about alternatives.]*

## **WHAT ABOUT CONFIDENTIALITY?**

1. *Required COG Statement:* Your blood [tissue samples] and your medical information will be given to the COG and will be identified with your name. In the future COG may give samples and information to other researchers. However, all other parties including employers, insurance companies, personal physicians, and relatives will be refused access to the information or to the samples. If COG does release your samples or information, they will be labeled with a code that does not reveal your name. However, COG will keep a record of your code number, and the code number could be used to link your samples or your information back to you or your relatives.

2. *Required OHSU Statement:* Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as: the OHSU Cancer Institute, the OHSU Institutional Review Board (IRB), the National Cancer Institute, the Food and Drug Administration (FDA), the Children's Oncology Group (COG), or XXX (the manufacturer of the study drug, XXX). If we publish the information we learn from this study in a medical journal, you will not be identified by a name or in any other way.

## **WHAT ARE THE COSTS?**

1. *If all costs are met by participant, modify the following statement as appropriate:* Your participation in this research study will be at your own expense. You or your insurance company will be responsible for all charges for (*hospitalization, drugs and their administration, operations, laboratory tests, imaging studies, physician fees, the reasonable and necessary cost of treatment for any unexpected complications, insurance co-payments and any other applicable costs*).

2. *When the costs to a patient or subject for an experimental procedure are expected to be high, an estimate of that cost should be given and insurance preauthorization is highly recommended.*

3. *When costs are shared, specify what costs will be covered by the sponsoring agency. Suggested wording:* Some of the procedures [devices, tests, drugs] in this study are part of the standard treatment for your condition and would be performed [given to you] even if you were not in this study. The costs for these procedures [devices, tests, drugs] will be billed to your insurance, or, if you are uninsured, will be billed to you. You will be responsible for any costs your insurance does not cover. You will not be responsible for the procedures [devices, tests, drugs] that are experimental and will not be billed for them.

4. *If subjects are compensated for expenses associated with participation, indicate how, the*

*amount, and how the amount will be prorated if the subject withdraws before completing the study.*

*5. If subjects are compensated for expenses associated with participation, indicate how, the amount, and how the amount will be prorated if the subject withdraws before completing the study.*

**COMMERCIAL DEVELOPMENT** *Unless COG has absolutely no intent to allow samples to be used for commercial development in the future this statement is required by OHSU:*

By consenting to participate, you authorize the use of your samples for the research described in the “**Why is this study being done ?**” and “**What is involved in this study ?**” sections of this document. In addition, you acknowledge that COG may make any lawful use of your samples, including, but not limited to, future research studies, destroying them, or transferring them to a public or private entity.

Samples obtained from you in this research may be used to make a discovery that could be patented or licensed to a company. There are no plans to provide financial compensation to you should this occur. However, should COG ever provide your samples to anyone else for research or commercial use, it will do so in such a way as to protect your privacy and confidentiality as stated in the “**What about confidentiality ?**” section of this document. Further, you will have no responsibility or liability for any use that may be made of your samples.

### **LIABILITY:**

To determine the correct liability language for the study, please access the liability language chart at [http://www.ohsu.edu/research/rda/irb/liability\\_language.shtml](http://www.ohsu.edu/research/rda/irb/liability_language.shtml).

### **WHAT ARE MY RIGHTS AS A PARTICIPANT?**

*Review to make sure statements are consistent with entire consent form*

*1. (Required OHSU Language):* You do not have to join this or any research study. If you do join, and later change your mind, you may quit at any time. If you refuse to join or withdraw early from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled. If you have any questions regarding your rights as a research subject, you may contact the Oregon Health & Science University Research Integrity Office at (503) 494-7887. You will be informed of any new findings developed during the course of this research study which may change the way you feel about being in the study.

*2. If the investigator is also the patient’s health care provider, use the following OHSU required statement:* Your health care provider is [one of the] investigator[s] of this research protocol, and

as an investigator is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way associated with this project. You are not under any obligation to participate in any research project offered by your physician.

3. *(Required OHSU Statement):* If you drop out of the study, physicians and hospital personnel will still take care of you and on your request identifying information will be destroyed and your DNA will not be used in any future research. However, if your genetic samples are being used in this research project at the time of your request, and if their withdrawal jeopardizes the success of this project, you may be asked for permission to continue to use them until the project is complete.

4. *Required COG statement:* A data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study. We will tell you about important new information from this or other studies that may affect your health, welfare, or willingness to stay in this study. You will be provided with this information as soon as it becomes available.

**WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**

Dr: \_\_\_\_\_ (telephone: 503-xxx-xxxx) has offered to answer any questions you may have about this study.

**WHERE CAN I GET MORE INFORMATION?**

You may call the NCI's Cancer Information Service at 1-800-4CANCER or TTY 1-800-332-8615

(Required OHSU Language): Please read each sentence below and think about your choice. After reading each sentence, mark the answer that is right for you

I give my consent to participate in the treatment part of this study, but I do not give my consent for the storage and future use of my blood/tissue samples.

Please mark one box:                      Yes                      No

I give my consent for my blood/tissue samples to be stored and used for this study only.

Please mark one box:                      Yes                      No

I give my consent for my blood/tissue samples to be used for this study and stored for possible use in future studies of but I wish to be contacted for permission prior to any future use.



