

**RESEARCH INFORMATION AND CONSENT FORM**

**Consent # and Arm**

**Study Title for Participants:**

***XXXX***

**COG PROTOCOL FULL TITLE:** XXXX

**Official Study Number for Internet Search on** [**http://www.ClinicalTrials.gov**](http://www.ClinicalTrials.gov) **:**

XXXX

**Persons responsible at this site:**

Montreal Children’s Hospital: Dre. Sharon Abish

CIUSSS de l’Estrie-CHUS: Dre. Josée Brossard

CHU Sainte-Justine: Dr. Yvan Samson

CHU de Québec-Université Laval: Dr. Bruno Michon

Funding: Children’s Oncology Group (COG)

It is a principle of medical ethics to obtain a written informed consent before starting any experimental procedure or treatment or participation in a research study.

If you are a parent or legal guardian of a child who could 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.

Your physician is one of the investigators conducting this clinical trial. Before taking the decision to participate in this research study, or at any time during your participation, you may wish to discuss with another physician who is independent from the study.

**OVERVIEW AND KEY INFORMATION**

You are being asked to take part in this research study because you have been diagnosed with XXXXX.

This study is called a clinical trial. A clinical trial is a research study that attempts to find or improve 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 participate.

**Taking part in this study is your choice. You have a choice between the usual treatment for yourdisease and this clinical trial.**

You have a choice between a standard treatment for yourdisease and this clinical trial. Please take your time to read this document and make your decision. You may want to discuss it with your doctor, family and friends about the risks and benefits of taking part in the study. We encourage parents to include their child in the discussion and decision to the extent that the child is able to understand and take part.

It’s important that you have as much information as you need and that all your questions are answered. See the “Where can I get more information?” section for resources for more clinical trials and general cancer information.

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

The treatment involves **XXXX**. The treatment on this study takes about **XXXX**.

In this study you will get **XXXX.**

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 doctor will not pick which treatment you get, but you will both know what your randomization assignment is.

All people who receive cancer treatment are at risk of having side effects. Cancer chemotherapy kills tumor cells. In addition to killing tumor cells, cancer chemotherapy also can damage normal parts of the body and cause side effects.

Common side effects of chemotherapy include nausea, vomiting, hair loss, and fatigue (tiredness). Drugs may be given to try to prevent or decrease nausea and vomiting. The most common serious side effect from cancer treatment is lowering of the number of normal blood cells resulting in anemia, increased chance of infection, and bleeding. Low blood counts are described in the COG “Family Handbook for Children with Cancer”. Parents will be taught more about caring for their child when his or her blood counts are low. 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. The risks of the individual drugs given as standard treatment are listed in [**Attachment XXXX**](#_heading=h.2s8eyo1) .

Arm XXXX of this study uses the investigational drug XXXX. Common side effects of this drug are XXXX.

The full list of risks for XXXX are available in the section “WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?”

You can ask your study doctor questions about side effects at any time.

We hope that this study will help you personally, but we do not know if it will. The potential benefits to you associated with participation in this study are described in the section “WHAT BENEFITS CAN I EXPECT FROM THIS STUDY?”

**This is the end of the “Overview and Key Information” section.**

**The rest of this form provides detailed information about the study and what to expect should you decide to participate. It is important that you understand the information in the informed consent before making your decision**.

**Please read, or have someone read to you, the rest of this document. If there is anything you don’t understand, be sure to ask your study doctor or nurse.**

**WHY ARE YOU BEING INVITED TO TAKE PART IN THIS STUDY?**

You are being invited to take part in this research study because you have been diagnosed with XXXX.

XXXX (copy from protocol).

This study is called a clinical trial. A clinical trial is a research study that attempts to find or improve treatment of a disease in human patients. This study is organized by the Children’s Oncology Group (COG). COG is an international research group that conducts clinical trials for children with cancer. More than 200 hospitals in North America (16 in Canada), Australia, New Zealand and Europe are members of COG.

**WHAT IS THE CURRENT STANDARD OF TREATMENT FOR THIS DISEASE?**

Standard therapy is treatment that most cancer doctors would recommend and that you would otherwise receive to treat your disease, even if you decide not to participate in a clinical trial. The standard treatment for XXXX is XXXX.

XXXX (copy from protocol).

**WHY IS THIS STUDY BEING DONE?**

**Participants are people who agree to take part in this study.**

Treatment for XXXX involves a common class of chemotherapy drugs called XXXX.

XXXX (copy from protocol).

**The overall goals of this study are to:**

XXXX (copy from protocol).

Other goals of this study include XXXX (copy from protocol).

**WHAT WILL HAPPEN ON THIS STUDY THAT IS RESEARCH?**

The treatment involves cancer fighting medicine called chemotherapy. The chemotherapy treatment on this study

XXXX (copy from protocol).

**Summary of Study Treatments**

XXXX (copy from protocol).

**Random Assignment to** XXXX

XXXX (copy from protocol).

**Risk Group Assignment**

XXXX (copy from protocol).

A diagram of treatment in this study can be seen on the next/this page.

Diagram of Study Treatment

XXXX

**Treatment that is Research**

Some parts of the treatment on this study are different from standard therapy. Treatment that is standard for XXXX is described in **Attachment XXXX.**

**Treatment for participants**

XXXX (copy from protocol).

**Required Research Study Tests**

Note regarding personal identifiers and samples/data sent to the researchers

Usually in research, samples and data are coded to protect research participants’ confidentiality. In this study, some of the results of testing done on your samples may be useful to determine the best treatment plan for you. In clinical care, these samples would be labelled with your name. As a result, some of your samples sent to COG as part of this study will include your name and birthdate and the results of some of the testing done on these samples will be returned to your doctor to use in planning your treatment. Your results may also be added to your medical record. Your information and samples will be kept in the United States in a secure, access limited database and facility.

**WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?**

**Treatment Risks**

**All people who receive cancer treatment are at risk for having side effects. In addition to killing tumor cells, cancer chemotherapy can damage normal tissue and cause side effects.**

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

**Common side effects of chemotherapy 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.**

Though combining chemotherapy medicines is the most effective way to kill XXX cells, side effects can also be increased when chemotherapy medicines 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 are described in the COG Family Handbook for Children with Cancer. Parents will be taught more about caring for their child when his or her blood counts are low.

**Risks of Study**

The use of XXXX instead of standard treatment may cause more complications.

XXXX could be less effective than the current standard treatment.

You may lose time at school, work or home and spend more time in the hospital or doctor’s office than usual. You may be asked sensitive or private questions which you normally do not discuss.

The treatmentused in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will be testing your blood and will let you know if changes occur that may affect your health.

There is also a risk that you could have side effects from the study drugs/study approach.

Here are important points about side effects:

* The study doctors do not know who will or will not have side effects.
* Some side effects may go away soon, some may last a long time, or some may never go away.
* Some side effects may interfere with your ability to have children.
* Some side effects may be serious and may even result in death.

You can ask your study doctor questions about side effects at any time.

Here are important points about how you and the study doctor can make side effects less of a problem:

* Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
* The study doctor may be able to treat some side effects.
* The study doctor may adjust the study drugs to try to reduce side effects.
* The study doctor will provide you with information about other drugs you may need to avoid while receiving the study drugs.

The tables below show the most common and the most serious side effects that researchers know about. There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

XXXX (Insert tables).

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

**Reproductive risks**

**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 birth control or not have sex while on this study. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some birth control methods might not be approved for use in this study. If you are a woman and become pregnant or suspect you are pregnant while participating in this study, please inform your treating physician immediately. Women should not breastfeed a baby while on this study. Also check with your doctor about how long you should not breastfeed after you stop the study treatment(s).**

**WHAT BENEFITS CAN I EXPECT FROM THIS STUDY?**

You may or may not personally benefit from your participation in this research project. However, we hope that the study results will contribute to the advancement of scientific knowledge in this field and help us find better treatments for patients.

**WHAT ARE MY CHOICES IF I DECIDE NOT TO TAKE PART IN THIS STUDY?**

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 in Attachment XXXX. It is Arm Aof this study.**
* **Taking part in another study.**
* XXXX

Please talk to your doctor about these and other options.

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

The total number of people enrolled on this study is expected to be XXXX.

In Quebec about XXXX people will participate in this study.

**HOW LONG IS THE STUDY?**

People in this clinical trial are expected to receive treatment on this study for about XXXX months. After treatment, you will have follow-up examinations and medical tests.

We would like to continue to find out about your health every year for about XXXX years after you enter this study. By keeping in touch with you for a while even after you complete treatment, we can better understand the long-term effects of the study treatments.

**IF I DECIDE TO TAKE PART IN THIS STUDY, CAN I STOP LATER?**

Yes, you can decide to stop taking part in the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your doctor will still take care of you.

If you decide to stop, let your study doctor know as soon as possible. However, if you decide to stop participating in the study, we encourage you to talk to the study doctor and your regular doctor first. It’s important that you stop safely. However, before you withdraw from the study, we suggest that you return to the clinic for a final evaluation, for safety reasons.

If you withdraw or are withdrawn from the study, no further data or biological samples will be collected. The information and [XXXX: add according to study: blood and tissue samples, audio and video recordings, and MRI images] already collected for the study will be stored, analyzed and used to ensure the integrity of the study, as described in this document.

Any new findings that could influence your health or your decision to stay in this research study will be shared with you as soon as possible.

**ARE THERE OTHER REASONS WHY I MIGHT STOP BEING IN THE STUDY?**

Yes. The doctor in charge of this research study, the Research Ethics Board, the funding agency, or the Sponsor may put an end to your participation without your consent if:

• Your health changes and the study is no longer in your best interest

* Your disease comes back during treatment
* You experience side effects from the treatment that are considered too severe

• New information becomes available that shows that another treatment would be better for you

• You do not follow the study instructions

• For women: You become pregnant or start breastfeeding while on the study

• The study is stopped by the National Cancer Institute (NCI), the Research Ethics Board, Health Canada, the Food and Drug Administration (FDA), or study sponsor (XXXX). The study sponsor is the organization who oversees the study

* The study drug becomes unavailable
* Administrative reasons to terminate the project

**WHAT ABOUT PRIVACY?**

During your participation in this study, the doctor in charge of the study and their research team will collect and record information about you in a study file. They will collect only the information needed to meet the scientific goals of the study.

The study file may include information from your medical charts including your name, sex, date of birth, ethnicity, past and present state of health, lifestyle, and the results of all tests, exams, and procedures that you will undergo during this research study.

The members of the local research team will access your medical record to collect the information needed for this research project.

To ensure your safety, a copy of the consent form and/or a study participation information sheet is included in your medical chart. The results of certain tests conducted as part of the research may be included as well, depending on the situation. As a result, any person or company to whom you give access to your medical chart will have access to this information.

You have the right to consult your study file in order to verify the information gathered, and to have it corrected if necessary.

The COG will do its best to make sure that the personal information in your research record will be kept private. However, they cannot guarantee total privacy. The *Children’s Oncology Group* has a privacy permit to help protect your records if there is a court case in the United States, but not in Canada. However, some of your medical information may be given out if required by law. If this should happen, the *Children’s Oncology Group* will do its best to make sure that any information that goes out to others will not identify who you are. Information about this Certificate of Confidentiality is included in **Attachment XXXX.** However, the sponsor and any international partners will nonetheless respect confidentiality rules equivalent to those in effect in Quebec and Canada, regardless of the country to which your data may be transferred.

For monitoring, control, safety, security, quality assurance, data analysis, regulatory approval and marketing of a new study drug, your study file as well as your medical charts may be examined and/or copied (without identifying information) by the following organizations:

* + The Children’s Oncology Group and its collaborators;
  + Representatives from the National Cancer Institute (NCI);
  + Canadian, American or International governmental regulatory bodies such as Health Canada, the Food and Drug Administration (FDA) in the US and international governmental regulatory agencies involved in overseeing research;
  + The research ethics committees of the Quebec hospitals where the research is happening or a person mandated by one of them;
  + Designated members of this institution;
  + The study sponsor

The organizations below may have access to your coded study data but not your hospital medical records:

* Companies that own the XXXX (XXXX).
* Any drug company supporting the study or their designated reviewers (safety data only)

All the above organizations adhere to confidentiality policies.

The data may be published or shared at scientific meetings; however it will not be possible to identify you.

Data will be stored for at least 25 years following the end of the study by the doctor in charge of this research study.

Some of your health information, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. Your personal information as a participant in this study will be kept confidential in a limited access, secure database and facility.

All data and study samples collected during this research study (including personal information and samples) will remain strictly confidential to the extent provided by law. You will be identified by a code number only. The key to the code linking your name to your study file will be kept by the doctor in charge of this research study.

However, some of your samples and data, including medical records, might be labelled with your initials and date of birth. Some of your medical records may be sent and/or uploaded into the COG and/or their affiliated NCI websites. In this study, it is also required that we send samples and data with your name, so that results can be returned to you. Usually in research, biological samples are identified by a study code. This exceptional situation for research is justified by the fact that the research lab may issue results that will be used for your care and treatment decisions.

In addition to storing data in the study database, data from studies that are publicly funded may also be shared broadly for future research with protections for your privacy, including sharing with commercial partners and your data will be coded. The goal of this data sharing is to make more research possible that may improve people’s health. Your study records may be stored and shared for future use in public databases. However, your name and other personal information will not be used. The Quebec research ethics committee and the researcher at your hospital will have no authority over the use made of your data in the future.

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

• You will not be asked if you agree to take part in the specific future research studies using your health information.

• You and your study doctor will not be told when or what type of research will be done.

• You will not get reports or other information about any research that is done using your information.

**WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?**

The standard therapy medication(s) administered as part of this research protocol will be provided to you. You will not have to pay for them, nor any of the tests or procedures that are part of the study.

The drug company that makes XXXX is supplying the drug at no charge for this study.

Even though it probably won’t happen, it is possible that the manufacturer may not continue to provide XXXX to the NCI for some reason. If this does happen, other possible options are:

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

If a problem with getting XXXX occurs, your study doctor will talk to you about these options.

You will not receive financial compensation for participating in this research study.New commercial products may be developed as a result of the research study in which you are taking part. However, you will not be entitled to any financial gain thereof.

The National Cancer Institute and the drug company that manufactures XXXX are providing money to the Children’s Oncology Group to do the research.

If you choose to enroll your child on this study, your hospital will receive some money from the COG to cover part of the costs related to conducting the research.

If you suffer side effects as a result of your participation in this research project, you will receive all necessary care that is covered by Quebec’s provincial health insurance plan (RAMQ) and by your medication insurance plan. You would be responsible for any costs that are not covered, for example uncovered fees from your health insurer’s co-payment terms. You will not be reimbursed for any costs incurred for taking part in this study.

For more information on clinical trials and insurance coverage, you can visit the Canadian Cancer Society’s Web site at <https://www.cancer.ca/en/cancer-information/cancer-type/childhood-cancer-information/long-term-survivorship/future-planning/?region=on>

**WHAT HAPPENS IF I AM HARMED BECAUSE I TOOK PART IN THIS STUDY?**

If you suffer harm of any kind following administration of the study drug, or any other procedure related to the research study, you will receive the appropriate care and services required by your state of health.

Neither the hospital, nor the sponsor of this protocol, the US National Institutes of Health or the COG, has a program for monetary compensation in case of harm resulting from your participation.

However, by agreeing to participate in this research project, you are not waiving any of your legal rights nor discharging the study doctor, the sponsor, or the institution, of their civil and professional responsibilities.

For more information on clinical trials and insurance coverage, you can ask the study doctor.

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

Your participation in this research project is voluntary. Therefore, you may refuse to participate. As mentioned before, you may also withdraw at any time, without giving any reasons, by informing the doctor in charge of this research study or a member of the research team. Your doctor is one of the researchers in this study. As such, your doctor’s interest lies both in your well-being and in the successful pursuit of this study. Therefore, before you sign up for the study or at any time thereafter, you may wish to consult with another doctor who is not part of this study. You are by no means obligated to participate in whatever research study is offered to you. Your decision not to participate in the study, or to withdraw from it, will have no impact on the quality of care and services to which you are otherwise entitled, or on your relationship with the clinical or research teams. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

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.

**WHERE CAN I GET MORE INFORMATION?**

We will tell you about any new information that may affect your health, well-being, or your willingness to stay in this study.A committee outside of COG closely monitors study reports and notifies the hospitals 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.

The**COG Family Handbook for Children with Cancer**has information about specific cancers, tests, treatment side effects and their management, adjusting to cancer, and resources. Your doctor can get you this Handbook, or you can download it at <https://www.childrensoncologygroup.org/index.php/cog-family-handbook>

The **Canadian Cancer Society** toll free at **1–888–939-3333** or <http://www.cancer.ca>

You may visit the NCI web site at <http://cancer.gov> for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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

A description of this clinical trial will be available at <http://www.ClinicalTrials.gov> as required by US law. This website will not include information that can identify you. At most, the web site will include a summary of the results. You can search this website at anytime.

A description of this clinical trial will also be available at: <http://canadiancancertrials.ca/>

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

In case of emergency, please contact the Hematology-Oncology department of your hospital or go directly to the closest emergency room**.**

If you have any questions or if you have a problem you think might be related to your participation in this research study, or if you would like to withdraw, you may communicate with the doctor in charge of this research study or with someone on the research team at the following numbers:

* Montreal Children’s Hospital, MUHC: Dre. Sharon Abish, at (514) 412-4445
* CIUSSS de l’Estrie-CHUS : Dre. Josée Brossard, at (819) 346-1110 ext. 12884
* CHU Sainte-Justine : Dr. Yvan Samson at (514) 345-4969 ext.2485
* CHU de Québec-Université Laval: Dr Bruno Michon at (418) 525-4444 ext. 40121

For any questions regarding your rights as a research participant in this study, or if you have comments or wish to file a complaint, you may communicate with the local service quality and complaints commissioner at :

* Montreal Children’s Hospital, MUHC : 514-412-4400, ext 22223
* CIUSSS de l’Estrie-CHUS : 1 866 917-7903 or at the following e-mail address : [plaintes.ciussse-chus@ssss.gouv.qc.ca](mailto:plaintes.ciussse-chus@ssss.gouv.qc.ca)
* CHU Sainte-Justine : 514-345-4749
* CHU de Québec-Université Laval: 418 525-5312, by email at plaintes@chudequebec.ca or online at "chudequebec.ca: formulaire de plainte ou d'insatisfaction"

**RESEARCH ETHICS COMMITTEE**

The Research Ethics Board of XXX approved this research study and is responsible for verifying all ethic aspects at all participating institutions in the health and social services network in Quebec.

**OPTIONAL RESEARCH TESTS**

This part of the consent form is about optional studies. They are separate from the main study described above.

Study doctors would like to learn more about XXX. These tests are important to help researchers learn more about XXX and may help children and young adults who have XXX in the future. The information learned would not change the way you are treated. You do not have to do these tests if you do not want to. You can still be in the study if you do not want to do these tests. At the end of this consent form, there is a place to record your decision about taking part in each test.

**Taking part in these optional studies is your choice.** You do not have to do these tests if you do not want to. You can still take part in the main study even if you say “no” to all of these studies. There is no penalty for saying “no.” If you sign up for, but cannot complete any of these studies for any reason, you can still take part in the main study. At the end of this consent form, there is a place to record your decision about taking part in each test.

If you decide you no longer want to participate in the optional studies, you can call a member of the study team who will let the study know. Then, any sample or data that remains will be destroyed or returned to your study doctor. This will not apply to any samples, data or related health information that have already been given to or used by researchers.

There is no direct personal benefit to you by participating in the optional parts of the research.

We hope that what we learn from doing these optional studies will be useful in the treatment of other patients who are diagnosed with this disease in the future.

Neither you nor your study doctor will be notified when research will be conducted or given reports or other information about any research that is done using your samples, unless something is discovered that could directly affect your health. If that happens your study doctor will be notified and will decide whether and how to contact you.

Your samples and data used for optional studies will be stored as described in the main study consent section on privacy.

**Neurocognitive Studies**

Cancer treatment can affect functions of the brain that relate to how we learn and remember, solve problems and even our social, emotional and behavioral functioning (this is called neurocognitive function).

XXXX (copy from protocol)

You may experience discomfort while you undergo these tests. If you do, please tell the person giving the test and they will stop. If you are filling in a questionnaire and feel uncomfortable, tell your doctor or the study team and they will help you.

**Specimen Banking**

We would like to take some XXX for future research. This is called “specimen banking” or “tissue banking”. A tissue bank is a lab where specimens (such as tumor, blood or bone marrow) are kept for use in future research studies. These samples would be drawn at the same time you are having a bone marrow procedure done for your routine medical care.

If you agree, ½ teaspoon to 1 teaspoon of additional bone marrow will be taken at the following time points.

* End of Induction 1
* End of Induction 2
* End of Intensification 1
* End of Intensification 2 (if applicable)
* End of Intensification 3 (if applicable)
* Between Day 15 and Day 100 after stem cell transplant (if applicable, 1 sample in this timeframe)
* Relapse

**Biobanking**

If you agree to Biobanking, your samples will be stored in the Biopathology Center at Nationwide Children’s Hospital, in a locked location. The Biopathology Center is supported by the NCI. The samples will be kept until they are used up, unless you request that they be destroyed. Some information from your medical record will also be kept in secure databases at the Biobank and updated from time to time. The information and samples will be kept under a code, not your name.

This is a publicly funded study. Samples from publicly funded studies are required to be shared as broadly as possible. Qualified researchers can submit a request to use the materials stored in the Biobank. The research may be about your type of cancer, about other cancers, or even about conditions unrelated to cancer. A science committee at the Children’s Oncology Group, and/or the National Cancer Institute, will review each request. The goal of this is to make more research possible that may improve people’s health. The samples and the information could be used by researchers anywhere in the world. Your sample will not be sold to third parties. Researchers will not be given your name or any other information that could directly identify you. Neither you nor your study doctor will be notified when research will be conducted or given reports or other information about any research that is done using your samples, unless something is discovered that could directly affect your health. If that happens your study doctor will be notified and will decide whether and how to contact you.

Right now, we don’t know what research may be done in the future using your samples. This means that:

● You will not be asked if you agree to take part in the future research studies using your health information.

● You and your study doctor will not be told when or what type of research will be done.

● You will not get reports or other information about any research that is done using your information.

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

Some of your genetic and health information may be placed in central databases that may be made available to qualified researchers, along with information from many other people.

Even without your name or other identifiers, your genetic information is unique to you. If you agree to Biobanking, there is a risk of a data security breach and that someone could trace the genetic information in a central database back to you. COG has put in place many safeguards in place to prevent it from happening, the risk may change in the future as people come up with new ways of tracing information. They could use that information in a way that could harm you.

Researchers believe the chance that someone could access and misuse your information is small. There are laws against the misuse of genetic information, but they may not give full protection. In some cases, misuse of the information could be used to make it harder for you to get or keep a job or insurance.

There can also be risks in learning about your own genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a study. Sometimes this is upsetting to families or they wish they didn’t know the information. We encourage you to discuss this study with your relatives before you decide whether to participate in the Biobanking part.

If you want to learn more about tissue research with banked specimens, the NCI website has an information sheet called “Providing Your Tissue For Research: What You Need To Know.” This sheet can be found at: <https://www.cancer.gov/publications/patient-education/providing-tissue>.

The samples for research will try to be taken at the same time as samples being taken for patient care. If possible, no extra procedures will be done solely for the purpose of getting these research samples. In the rare cases that it is necessary, we will ask for your permission.

Possible inconveniences could include a longer time needed to acquire the extra sample, more pain or a higher risk of infection. The amount of sample taken is safe. These procedures can be unpleasant and can cause bruising, discomfort and rarely, an infection. The amount of samples taken is safe.

N.B.: The COG becomes the owner of any tissue or samples and the information related to them once you consent to their storage and use for future research (this project). Accordingly, the Quebec research ethics committee and the researcher at your hospital will have no authority over the use made of your samples in the future.

**OPTIONAL STUDIES CHOICE**

The choice to participate in optional research studies is up to you. No matter what you decide to do, it will not affect your care. You can still be a part of the main study even if you say ‘No’ to taking part in any of these optional research studies.

If you have any questions, please talk to your doctor or nurse, or call the patient representative at the number included in the main consent.

Please read the information below and think about your choices. After making your decisions, check “Yes” or “No”, then add your initials and the date after your answer.

In the consent signing sections, the term "I" or “my” mean myself or my child.

1. XXXX (copy from protocol).

Yes ☐ No ☐ \_\_\_\_\_\_\_\_ / \_\_\_\_\_\_\_

Initials Date (DD-MMM-YYYY)

1. XXXX (copy from protocol).

Yes ☐ No ☐ \_\_\_\_\_\_\_ / \_\_\_\_\_\_\_ Initials Date (DD-MMM-YYYY)

1. XXXX (copy from protocol).

Yes ☐ No ☐ \_\_\_\_\_\_\_\_ / \_\_\_\_\_\_\_

Initials Date (DD-MMM-YYYY)

**CONSENT AND ASSENT FORM**

I have reviewed the Information and Consent Form. Both the research study and the Information and Consent Form were explained to me.My questions were answered, and I was given sufficient time to decide. After reflection, I consent to participate in this research study in accordance with the conditions stated above, including the use of all personal data and samples collected.

I authorize the research study team to access my medical chart to collect the information relevant to the research study from the hospital where the research study is conducted, as well as from other hospitals or clinics where I might get treatment and the follow-up. This also includes information in the Dossier Santé Québec (DSQ).

I will receive a signed and dated copy of this consent form including all pages, addendum and attachments. I may also request a copy of this research protocol (complete study plan).

**CHILD ASSENT** N/A ☐

Child Name Assent of child able to understand Date (DD-MMM-YYYY)

(Print) the nature of the research project

(Child’s signature)

OR verbal assent obtained by:

Name of person who obtained verbal assent (Print)

**PARENT/GUARDIAN CONSENT OR PARTICIPANT AT AGE OF MAJORITY AT TIME OF CONSENT**

Name of parent/Guardian/Participant 18+ Signature Date (DD-MMM-YYYY)

(Print)

**PERSON OBTAINING CONSENT**

I have explained the research study and the terms of this Information and Consent Form to the research participant and/or his parent/guardian, and I answered all questions asked. I explained that participation in a research project is voluntary and that they can stop participating at any time they choose.

Name of person obtaining consent (Print) Signature  Date (DD-MMM-YYYY)

**INTERPRETER**

Interpreter used? Yes ☐ No ☐ N/A ☐

If an interpreter was used, language of interpretation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Interpreter’s Name (Print) Signature  Date (DD-MMM-YYYY)

**ADDENDUM TO CONSENT FORM**

**Participant who has now become an adult (18+)**

Today, I reviewed the information and consent form that my parents signed on my behalf when I enrolled in this research project and a copy of that signed consent was given to me.

I agree to continue my participation in this research project and, if applicable, keep participating in optional studies.

I understand that my participation is voluntary and that I can stop participating in this research project at any time I choose.

I authorize the research team to consult my medical records to collect the information relevant to this project.

|  |
| --- |
| ***Main Consent Signature*** |
| Name of participant (18+) (Print) Signature  Date (DD-MMM-YYYY)    Name of person obtaining consent (Print) Signature  Date (DD-MMM-YYYY) |
|  |
| ***Optional Studies*** |
| 1. XXXX (copy from protocol).  NA Yes ☐ No ☐ \_\_\_\_\_\_\_\_ / \_\_\_\_\_\_\_  Initials Date (DD-MMM-YYYY) |

|  |
| --- |
| ***Interpreter*** |
| Interpreter used? NA ☐ Yes ☐ No ☐  If an interpreter was used, language of interpretation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_    Interpreter’s Name (Print) Signature  Date (DD-MMM-YYYY) |

**ATTACHMENT 1**

**ATTACHMENT 2**

**ATTACHMENT 3**

**Certificate of Confidentiality**

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 subjects. The Certificate protects against the involuntary release of information about subjects 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 subject or the researcher may choose to voluntarily disclose the protected information under certain circumstances. For example, if the subject 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.