

**RESEARCH INFORMATION AND CONSENT FORM**

**Title :**

**Name of Participant :**

**Persons responsible :**

* Montreal Children’s Hospital- McGill University Health Center: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* CHU Sainte-Justine : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Other institution (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Funding Source:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

**Example**

The \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ department/service participates in research studies to try to improve treatments for children with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Today, we are inviting you to take part in a research study. Please read this information to help you decide if you want to participate in this research project. It is important that you understand this information. We encourage you to ask questions. Please take all the time you need to make your decision.

We encourage parents to include their child in the discussion and decision making to the extent that the child is able to understand.

In this research information and consent form, “you” means you or your child.

**WHY IS THIS STUDY BEING DONE?**

Specific to each project.

* Context and importance of the research

## Example

You have a disease/illness called \_\_\_\_\_\_\_\_\_\_\_\_. This illness can cause \_\_\_\_\_. The standard treatment for this illness is \_\_\_\_\_\_. Unfortunately, many children don’t respond to this treatment. Recent studies have shown that an experimental medicine called \_\_\_\_\_\_\_\_\_\_ might improve the health of these patients.

* Goals of the research;

## Example

You are being invited to participate in a research study that aims to compare an experimental medication X to medication Y which is the standard treatment.

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

**Examples**

About\_\_\_ patients will take part in this study including approximately \_\_\_\_\_\_ participants from this hospital.

About \_\_\_ participants from different hospitals, here, and elsewhere in the world will take part in this research study.

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

Specific to each project.

* Tests to ascertain eligibility
* Interventions and activities that are specific to the research

Examples :

* Blood test, ultrasound, taking a medication, answering a questionnaire, etc.
* Randomization (chance of being placed in either group, indication if neither the participant nor the researcher will know to which group the participant is assigned until the project has been completed)
* Placebo (a substance that looks like the study drug but that contains no active ingredients.)
* Control group
* Number of procedures
* Duration of each procedure
* Location(s) where procedure(s) will take place.
* Distinguish between any aspects of the project that are part of standard treatment and those that are for the purposes of the research
* Access to the participant’s medical record

### *Example*

The research team will consult your medical record to obtain information relevant to this research.

* The follow up period

\* Reminder to research team: A participant’s consent for access to his medical record for the purpose of study, teaching or research, must be given in writing. It must be free and informed and is granted for a precise purpose. The consent is valid only for the time needed to achieve the purpose for which it was granted or, in the case of a research project approved by a research ethics committee, for the time specified by them, if any. (art. 19.1 *of the Loi sur les services de santé et services sociaux).*

\*\* Reminder to research team: It is not necessary to state the inclusion criteria in the consent form. This only lengthens the form unnecessarily.

FOR HOW LONG WILL YOU PARTICIPATE IN THIS STUDY?

Specific to each study

***Example***

Participants in this clinical trial will receive (if pertinent add “experimental”) treatment for a period of \_\_\_\_ months.

We would like to continue to check on your health every year for about \_\_\_years after your participation in the research project. Keeping in contact with you for some time after your active participation ends may help us to learn about the long-term effects of the experimental treatment being studied.

Your doctor or the doctor in charge of this research project can also decide to take you off this study, namely:

o If she or he believes it would be in your best interests;

o If your disease gets worse;

o If you have side effects that she or he believes are too dangerous;

o If new information shows that another treatment, more appropriate for you, becomes available.

o If you do not fulfill the expectations for your participation, as described in this form.

WHAT ARE THE RISKS?

Specific to each project

* All foreseeable risks or inconveniences, be they physical, psychological, social or other, as well as the possibility of unknown risks to the participant and his family.

*Example*

The samples will be taken during routine blood tests done for the participant’s clinical care. No extra procedures will be done just for research. A possible inconvenience may be that the blood test may last a little longer, cause a little extra discomfort, have a higher risk of infection. The amount of blood taken is safe.

*Example*

There is no inconvenience other than the time it takes to answer the questionnaire.

*Example*

The blood test is unpleasant and can cause a bruise, discomfort and rarely an infection. The amount of blood taken is safe.

*Example*

Reproductive Risks

Women should not get pregnant and men should not conceive a baby during their participation in this research project because the medication being studied could be dangerous for an unborn baby. If you or your partner are old enough to get pregnant, you should use a birth control method or abstain from having sex during the time you are participating in this research study.

Some birth control methods are not recommended while you are taking part in this research. Talk to your doctor about which birth control method would be best for you and also for how long you should use it.

Women must use birth control during the research project but also for \_\_\_\_\_ months after their participation ends.

Men must use birth control during the research project but also for \_\_\_\_\_ months after their participation ends.

Women should not breastfeed a baby while participating in the research. Ask your doctor how long you must wait after the research is finished before you can start to breastfeed.

*Example*

Unknown Risks

Participation in this research project may also have other risks that we do not know or have not predicted.

* Security and comfort measures taken to minimize and manage risks and inconveniences.

For example: presence of a physician during the procedure, phone number to call in case of emergency, do not take other medications, do not drink grapefruit juice to avoid a medication reaction, etc.

\* Reminder to research team:  A minor may participate in research that could interfere with the integrity of his person only if the risk incurred, taking into account his state of health and personal condition, is not disproportionate to the benefit that may reasonably be anticipated. (art. 21 Civil Code of Québec).

\*\* Reminder to the research team: in the context of research, all risks associated with the procedures or steps that are part of the protocol must be divulged, including any related to the choice of research methodology, tests, diagnostic and quality control mechanisms, etc..

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

*Example – No direct benefit*

There is no direct benefit to you for participating in this research. We hope that what we learn from doing this study will help us find better ways to treat patients with this disease in the future.

*Example – Possible direct benefit*

We hope that you will get some personal medical benefit from participation in this clinical trial, but we cannot be certain. One possible benefit we are hoping for is \_\_\_\_\_\_\_\_\_\_\_\_\_. We also hope that what we learn from doing this study will help us find better ways to treat patients with this disease in the future.

\* Reminder for the research team: A minor may participate in research only if, where he is the only subject of the research, it has the potential to produce benefit to his health or only if, in the case of research on a group, it has the potential to produce results capable of conferring benefit to other persons in the same age category or having the same disease or handicap. (art. 21 Civil Code of Québec).

WHAT OTHER OPTIONS ARE THERE?

### *Example*

Instead of participating in this research project, you could choose the standard treatment, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Please discuss the different options you have with your doctor.

Example

Instead of participating in this research project, you could choose one of the following options:

• Receive the standard treatment.

• Participate in another research project if available.

• Receive comfort care, sometimes called palliative care. This kind of care aims to reduce pain, fatigue, appetite problems and other kinds of symptoms caused by the illness. Palliative care does not actively treat the illness, instead it aims to help you feel as well as possible and to enable you to have a life as active and comfortable as possible.

Please talk to your doctor.

\* Reminder for the research team: This clause will not be relevant for all projects. Verify according to the context.

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

### Who will pay for the medication or the experimental treatment being studied?:

*Example*

### The study medication(s) will be given to you by \_\_\_\_\_\_\_\_\_\_\_\_\_\_. You will not have to pay for it (them).

### Who will pay for the care, medications and treatments if there are side effects:

### *Example – Research with no funding by private enterprise*

In case of side effects resulting from the study medication or from procedures required for this research project, you will receive all necessary medical care covered by the Quebec’s provincial health insurance plan (RAMQ) or by your private drug insurance plan. You will be responsible for paying the portion of any costs not covered.

###  *Example – Research financed by private enterprise – best practice negotiated in the contract*

In case of side effects resulting from the study medication or from procedures required for this research project, you will receive all necessary medical care without any cost to you. The company, (name) will reimburse all medical costs resulting from this care upon receipt of the medical bills.

### *Example – Research financed by private enterprise – acceptable practice best practice negotiated in the contract*

In case of side effects resulting from the study medication or from procedures required for this research project, you will receive all necessary medical care without any cost to you. The company, (name) will reimburse all medical costs resulting from this care and not already covered by Quebec’s provincial health insurance plan (RAMQ), upon receipt of the medical bills.

### \* Reminder to the research team : For research with no physical risks, this clause is not relevant.

\*\* Reminder to the research team : Any clause that attempts to release the researcher, the sponsor or the institution from their legal or professional responsibilities is unacceptable, both legally and ethically.

\*\*\* Reminder to the research team : When a research project is financed by a company, the REB requires, as a minimum standard, that the company commits to paying any costs that would not be covered by the Régie d’assurance-maladie du Québec (RAMQ). Best practice remains that the company pays for all of the medical costs engendered by this necessary care.

**ARE THERE OTHER FINANCIAL ASPECTS?**

*Example*

You will not be reimbursed for other costs incurred during your participation.

*or*

*Example*

You will receive \_\_\_\_\_\_\_$ to reimburse you for out of pocket expenses or inconveniences as a result of your participation. If you decide to stop being in the study, you will be reimbursed an amount in proportion to your participation.

*Example* – When biological samples are used and commercialization of the research results may be foreseeable, even in the long term.

Part of this research project is to collect biological samples. New commercial products could be developed from these samples and generate profits. However, you will not have a right to share in any profits.

* Reminder to the research team : A person's participation in research may not give rise to any financial reward, but they may be compensated for inconveniences suffered. (Art. 25 Civil Code of Québec)

HOW IS PRIVACY ENSURED?

*Example*

All information obtained during the study will be kept confidential as required or permitted by law. Your identity will be protected by replacing your name with a research number. Only the research team at your own hospital will have access to the code linking your name to this number.

In order to ensure your protection and quality control of the research project, the following organizations could consult your research and medical records:

o The sponsor(s) of this project;

o Government regulatory bodies such as Health Canada;

o The research ethics committees of the Quebec hospitals where the research is happening or a person mandated by one of them;

o The drug company that makes (study drug) or its representatives.

These organizations all adhere to a confidentiality policy.

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

The principal investigator at your hospital will be responsible for securely storing all the research data for (7 or 25) years.

Only coded data will be sent and stored by (name of company or coordinating center)

Add if the research may have clinical impact

*Example*

For your safety, a copy of this signed consent form and some information about the research, ex. name of any experimental medications given, will be filed in your medical record.

If biological samples, questionnaires, recordings, videos or photos were collected

*Example*

The \_\_\_\_\_ [samples, questionnaires, recordings. videos, photos etc.] will be destroyed \_\_\_ years after the completion of the research project.

\* If the research team plans to collect particularly sensitive information (ex. On marginalized behaviours, sexual, criminal etc.) confidentiality should then be strictly protected (i.e. not simply in accordance with legal limits). E.g. « All information collected will be kept strictly confidential. »

\* Reminder to the research team: It is only relevant to mention Health Canada and/or the FDA in the case of clinical trials involving medications, medical instruments or natural health products.

\*\* Reminder to the research team: For clinical trials, records must be kept for 25 years(art. C.05.012, Règlement sur les aliments et drogues). Projects affiliated with University of Montreal or McGill must be kept for 7 years (university policies).

**IS YOUR PARTICIPATION VOLUNTARY?**

*Example*

Yes. Taking part in this study is voluntary. You may choose not to be in this study. You can decide to stop being in the study at any time. If you decide not to be in this study, or to stop participating in the study later on, this will not affect the quality of care you receive from your doctor.

 We will tell you about any new information that may affect your health, well-being, or your willingness to stay in this study.

**Add if applicable i.e. Clinical trials**

*Example*

If you decide to stop taking a study drug, please speak with a member of the research team who will help make sure you stop safely. It is possible that the research team will ask you to come for a final visit.

If you stop participating, no new information about you will be collected. Data from already completed analyses will be kept.

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

*Example*

If you have any questions about this research project or if you suffer any problems you believe are related to your participation in this research, you can call the researcher responsible for the project in your hospital:

CHU Sainte-Justine : Dr.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

Montreal Children’s Hospital: Dr. \_\_\_\_\_\_\_\_\_\_ at (514) 412-XXXX

In case of emergency, please go directly to the closest emergency room.

If you would like information about your rights related to your participation in the research, you may contact the hospital Ombudsman (Patient Representative):

• Montreal Children’s Hospital : 514-412-4400, poste 22223

• CHU Sainte-Justine : 514-345-4749.

• CHU de Québec au 418-654-2211

**WHERE CAN I GET MORE INFORMATION?**

*Examples*

For Clinical Trials (in english only) : A description of this clinical trial is available at <http://www.clinicalTrials.gov>, in accordance with American and Canadian law. This website will not contain any information that would identify you. It will provide a summary of the research results once ready. You may search the website at any time.

You may ask to receive a copy of the results of this research project; these will only be available after the entire project has been completed.

You will receive a signed copy of this form. You may ask the research team questions at any time.

**RESEARCH ETHICS COMMITTEE**

*Example*

The research ethics committee of (hospital name) approved this project and will monitor the project.

CONSENT AND ASSENT FORM

Title of this research project:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I have been explained what will happen on this study. I read the information and consent form of \_\_\_ pages including the annexes and was given a copy to keep. I was able to ask my questions and they were answered to my satisfaction. After thinking about it, I agree to, or I agree that my child will, participate in this research project.

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

In no way does consenting to participate in this research study waive your legal rights nor release the sponsor or the institution from their legal or professional responsibilities if you are harmed in any way.

Name of participant Assent of minor, capable of understanding Date

(Print) the nature of the research (signature) or

 Verbal assent of minor obtained by:

Name of parent(s) or legal guardian Signature Date

(Print)

Name of participant (18 years +) Signature Date

(Print)

I have explained to the participant and/or his parent/legal guardian all the relevant aspects of this study. I answered any questions they asked. I explained that participation in a research project is free and voluntary and that they are free to stop participating at any time they choose.

Name of Person obtaining consent (signature) Date

(Print)

**Addendum to consent form**

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

**Title of research project : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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.

I understand that my participation is free and 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.

 (Adapt to the context) If I withdraw, any remaining samples or data that has not already been analyzed will be destroyed.

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

Name of participant  Signature  Date

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

Name of person Signature Date

obtaining consent