

**PEDIATRIC 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.

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

\* 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.

**IS ANY COMPENSATION BEING OFFERED?**

*Compensation in the form of an amount proportional to research participation*

You will receive [*indicate the compensation offered*: an amount of X$ per study visit, for a total of X visits, for a total amount of X$] for costs and inconveniences incurred during this research study. If you withdraw from the study, or are withdrawn before it is completed, you will receive compensation proportional to the number of visits you have completed.

 and/or

*Compensation in the form of reimbursement or for coupons covering expenses*

You will be reimbursed for the costs of [*choose:* travel, meals, parking…] related to your participation in this study. [You will be reimbursed upon presentation of receipt OR paid by a coupon which you will be given]-[specify a time.]

 **OR**

*No compensation*

You will not receive financial compensation for participating in this research study.

 **AND**

*Medications offered*

[Optional: The research drug X will be offered to you for free for the duration of this research study.]

 AND

*Potential for commercialization*

The results of this study following your participation could lead to the creation of commercial products. However, you will not receive any financial benefits.

* 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?

*Collection - Who? Reason for which personal information is requested*

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

*AND*

*Collection - What?*

*The study file may include information from your medical chart [Optional: including your identity,] concerning your past and present state of health, your lifestyle, as well as the results of the tests, exams, and procedures that you will undergo during this research project.*

*[OPTIONAL: Your research file could also contain other information, such as your name, sex, date of birth and ethnic origin.]*

 *and*

*Where applicable:*

*The [choose: blood sample, tissues, x-rays, MRI, etc.,] will be sent to [insert the name or responsible party…] and conserved for [insert length of time] for the exclusive objectives of this study and then destroyed [or destroyed after analysis.]*

*AND*

*Data storage - Protection*

*All the information collected during the research project will remain strictly confidential to the extent provided by law. [To be adapted based on the study protocol: You will only be identified by a code number. The key to the code linking your name to your study file will be kept by the study doctor.]*

 *and*

*To ensure your safety, a copy of this information and consent form [Specify the type of information: as well as the results of tests conducted as part of this research study (see section “What” ex. the result of blood tests) will be placed in your medical chart. As a result, any person or company whom you give access to your medical chart will have access to this information.*

*AND*

*Data sharing*

 *The study doctor will forward your coded data to the sponsor or their representatives.*

 *and*

*People authorized to access study data*

*The Sponsor may share the coded study data with their commercial partners.*

*[To be adapted based on the study protocol: However, the sponsor and any international partners will respect the confidentiality rules in effect in Quebec and Canada, regardless of the country to which your data may be transferred.]*

 *and*

*Duration of data storage*

*The study data will be stored for 25 years by the study doctor [where applicable : and the study sponsor or the funding agency.]*

*AND*

*Dissemination of results*

*The data may be published or shared during scientific meetings, however it will not be possible to identify you.*

*AND*

*Right of access for monitoring and safety, including “Mesure 9”*

*For monitoring, control, safety, security, and marketing of a new study drug, your study file as well as your medical charts may be examined by a person mandated by Canadian or international regulatory authorities, such as Health Canada, as well as by representatives of the study sponsor, the institution, or the Research Ethics Board. All these individuals and organizations adhere to policies on confidentiality.*

*AND*

*Right of access of the participant (Law on Access to Information)*

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

 *and*

*Where applicable: However, in order to protect the scientific integrity of the research project, you may only have accessing to certain information before the project is ended once this project has ended may require that you be withdrawn from the study.*

**IS YOUR PARTICIPATION VOLUNTARY AND CAN YOU WITHDRAW?**

*Voluntary participation and the right to withdraw*

Your participation in this research project is voluntary. Therefore, you may refuse to participate. You may also withdraw from the project at any time, without giving any reason, by informing the study doctor or a member of the research team.

**AND**

*Consequences for care*

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 study doctor or clinical team.

**AND**

*Withdrawal of the participant from the study by the investigator or by others*

The study doctor, the Research Ethics Board, the funding agency, or the Sponsor may put an end to your participation without your consent. This may happen if new findings or information indicate that participation is no longer in your interest, if you do not follow study instructions, or if there are administrative reasons to terminate the project.

**AND**

*Means of withdrawal*

However, before you withdraw from the study we suggest, [To be adapted based on the study protocol: that you return to the clinic for a final evaluation, for safety reasons.]

 **AND**

*Consequence of withdrawal for data storage*

If you withdraw or are withdrawn from the study, the information collected during the study will nonetheless be stored, analyzed or used to protect the scientific integrity of the research project.

**AND**

*New information*

Any new findings that could influence your decision to stay in the research project will be shared with you as soon as possible.

**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**

*Multicenter study*

*The Research Ethics Board of [insert name of institution to which the REB is affiliated] approved this study and is responsible for monitoring it at all participating institutions in the health and social service network in Quebec.*

 *Or*

*Local study*

*The Research Ethics Board of [insert name of institution to which the REB is affiliated] approved this research and is responsible for the monitoring of the study.*

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 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.

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.

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**

**Consent to participation in an extension phase (if applicable)**

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

My child has completed the 52 week study and is eligible to extend his/her participate until week 252 (including the 52 weeks already completed) i.e. for about 4 more years.

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

I understand that the extension involves my child taking the same experimental drug and that the study procedures and visits will be the same until the study ends at 252 weeks.

A new table explaining what is involved at each study visit from week 60-252 was provided to me.

I agree to continue my child’s participation in this research project.

I understand that my child’s participation is free and voluntary and that I can stop his/her participation in this research project at any time I choose.

I authorize the research team to continue to consult my child’s medical records 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)

I have explained to the participant and/or his parent/legal guardian all the relevant aspects of the extension to the original 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