

**NOTE for the research teams**

The areas italicized and highlighted in grey are to guide the research team in the drafting of an appropriate informed consent form. Please remove them from the final informed consent form sent in to the Research Ethics Board.

**RESEARCH INFORMATION AND INFORMED CONSENT FORM**

**Research Study**:  *insert name of study*

**Persons responsible :**

* Montreal Children’s Hospital- McGill University Health Center:  Insert the name (s)
* CHU Sainte-Justine :  Insert the name (s)
* Insert the name (s) of the other institution (s) (if not applicable, delete)  :  Insert the name (s)

**Funding Source:**  Insert the name

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

The  Insert the name of the departmen / service   participates in research studies to try to improve treatments for children with  Insert the name of the illness/condition . 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 informed consent form, “you” means you or your child.

**WHY IS THIS STUDY BEING DONE?**

Specific to each project (to be adapted)

*Context and importance of the research*

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  Insert the name of the study drug  might improve the health of these patients.

**WHAT ARE THE OBJECTIVES OF THE RESEARCH?**

You are being invited to participate in a research study that aims to  insert here the objective, for example: compare an experimental medication X to medication Y which is the standard treatment  .

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

About  Insert the app. number of participants  participants will take part in this study including approximately  Insert the app. number of participants  participants from this hospital.

**OR**

About  Insert the app. number of participants 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 (to be adapted)

*Tests to ascertain eligibility*

Add text. For examplee: This study has three (3) differents stages:

1- Assessment of your eligibility: During this period which can last up to 28 days, we will assess if you can participate in the research project. If you are not eligible to participate in this study, we will tell you why.

2- Treatment period: During this period which can last up to 4 month, you will recive the experimental drug (to adapt: or the placebo).

3- Follow-up: During this period which can last up to 12 monts (1 year), we will follow your health status.

*Interventions and activities that are specific to the research*

 Describe the tests and procedures related to the research study. For example:

* 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*

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 project (to be adapted)

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.

WHAT ARE THE RISKS?

Specific to each project (to be adapted)

*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.*

*Examples. To be adapted.*

*Blood tests:*

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

**OR**

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.

*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.

*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.*

Specific to each project (to be adapted)

 Insert text: 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 the 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?

*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.

*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  insert text  . 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.

WHAT OTHER OPTIONS ARE THERE?

Specific to each project (to be adapted)

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.

**IS ANY COMPENSATION BEING OFFERED?**

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

You will receive an amount of $      per visit scheduled as per protocol, for a total of       visits, for a total amount of $      , as compensation for costs incurred during your participation in this research study. If you withdraw from the study (or are withdrawn) before it is completed, compensation will be proportional to the length of your participation.

**AND/OR**

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

Your expenses for  choose: travel, meals, parking, etc. related to your participation in this research study will be  choose: reimbursed upon presentation of receipts OR paid by a coupon which will be given to you at (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  name of the drug  will be offered to you free of charge for the duration of this research study.

\* 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)

**SHOULD YOU SUFFER ANY HARM**

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

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

HOW IS PRIVACY ENSURED?

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

The study file may include information from your medical charts including your  choose: identity, such as your name, gender, date of birth, ethnicity  , past and present health status, lifestyle, and the results of all tests, exams, and procedures that will be performed.

All study data collected during this research study (including personal information and samples) will remain 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.

To ensure your safety, a document indicating your participation in this study  specify the type of information, e.g., a copy of the Informed Consent Form OR a data 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.

The doctor in charge of this research study or a member of the research team will forward your coded data to the sponsor or its representatives.

However, the sponsor and any partners outside of Quebec are required to respect confidentiality rules equivalent to those in effect in Quebec and Canada, regardless of the country to which your data may be transferred.

Study data will be stored for at least 25 years following the end of the study by the doctor in charge of this research study where applicable, choose : and the study sponsor and/or funding agency . *[Optional : (specify a different duration for study samples) ]*

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

For monitoring, control, safety, security, and approval of the study drug by regulatory agencies, 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 authorized representatives of the study sponsor, the institution, or the Research Ethics Board. All these individuals and organizations will have access to your personal data, but they adhere to a confidentiality policy.

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

[*Where applicable*: However, to protect the scientific integrity of this study, you may have to withdraw from the study if you access certain information before the study ends.

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

Your participation in this research study is voluntary. Therefore, you may refuse to participate. 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.

[*Where applicable*:] Your doctor is one of the investigators in this study. As such, your doctor’s interest lies primarily in your well-being and also in the successful pursuit of this study. Therefore, before you sign up for the study pr 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 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 teams providing them.

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. This may happen if new findings or information indicate that participation in this research study is no longer in your best interests, if you do not follow study instructions, or if there are administrative reasons to terminate the study.

However, before you withdraw from the study, we suggest [*to be adapted based on the study*  *protocol*:] that you take part in a final evaluation, for safety reasons.

If you withdraw or are withdrawn from the study, no further data or biological samples will be collected. However, the information  [*if relevant]* and biological material,blood and tissue samples, audio and video recordings, images and MRI 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 acquires during the course of the study that could influence your decision to continue your participation will be shared with you quickly.

*Optional part* [If scientifically warranted – see if applicable or not]

You have the right to modulate your withdrawal from the study at any time, by [*to be adapted based on the study*  *protocol*:]:

* Stopping the study drug,
* Stopping the follow-up visits on site,
* Stopping telephone follow-up,
* Allowing only medical chart information to be transmitted to the sponsor, or
* Withdrawing from the study completely.

**POSSIBILITY OF COMMERCIALIZATION**

The results of the research derived in part from your participation in the study may lead to the development of new commercial. However, you will not be entitled to any financial gain thereof.

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

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 number:

CHU Sainte-Justine : Dr.  insert the name and the phone number

Montreal Children’s Hospital: Dr.  insert the name and the phone number

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

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:

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

• CHU Sainte-Justine : 514-345-4749.

The Research Ethics Board of [*insert name of institution with which the REB is affiliated*] has given ethics approval to this research study and is responsible for monitoring the study at all participating institutions in the health and social services network in Quebec.

or

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

**WHERE CAN I GET MORE INFORMATION?**

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.

**CONSENT AND ASSENT FORM**

**Research Study**: *[insert name of study]*

I have reviewed the Informed Consent Form. Both the research study and the Informed Consent Form were explained to me. My questions were answered, and I was given sufficient time to decide. After reflection, I consent to participate, or that my child will 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 study team to access my medical chart or the medical chart of my child.

In addition, I authorize the researcher or research team to inform the family doctor or treating physician, in writing, that I am/my child is taking part in this research study, and to send them all relevant information.

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 the research study and the terms of this Informed Consent Form to the research participant, and I answered all questions asked.

Name of the person obtaining consent Signature Date

**SIGNATURE OF WITNESS**

**YES □ NO □**

A witness’ signature is required in the following cases:

Reading disability or inability to read – The witness (impartial) signing below attests to the fact that they read the Informed Consent Form, that the research study was precisely explained to the participant, and that the participant seems to have understood it.

Foreign language (participant does not understand the language in which the Informed Consent Form was written) – The signatory attests to acting as interpreter for the participant throughout the consent process.

Name of witness Signature Date

**Addendum to consent form (*Where applicable)***

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

**Research Study**: *[insert name of study]*

Today, I reviewed the informed 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

***If applicable: Addendum for use if the general data protection regulation (GDPR) applies***

**Additional Information on Data Privacy Following the Application of the *General Data Protection Regulation* (GDPR)**

**Research Study**:  Insert the name of the study

**Sponsor:**  Insert name of the sponsor and address of sponsor's head office in Europe

Dear Sir/Madam,

The international sponsor of this research study,  insert name of sponsor *,* has a head office in Europe. As such, the sponsor must comply with the *European Union General Data Protection Regulation* (GDPR). The GDPR gives you additional rights that are not specified in Canadian and Quebec legislation and that therefore do not appear in the Informed Consent Form that you signed for the research study stated above. For more information, see below.

As per the GDPR, you have the following rights to data privacy, in addition to those specified in the Informed Consent Form you signed:

* Should you request corrections to the data collected about you during the project, please note that you have the ***right to restrain*** the processing and use of that data while your request is being evaluated. For example, you may ask that your data not be processed until your request has been reviewed.
* You have the ***right to request a transfer of*** your study data to yourself or to anyone else in any commonly used, and accessible format, such as a computer-readable.
* You have the ***right to file a complaint*** with a European data protection authority, such as  insert the name and contact information of a competent European authority designated by the study sponsor .
* You have the ***right to request the deletion*** of your study data. These will be deleted if no longer needed or if there is no other legal requirement for their use.

If you have any questions, please contact the doctor in charge of this study.