**Interventional Informed Consent form: Information and template FOR PArticipants**

**DRAFT Version Date: November 14, 2019**

The Interventional Informed Consent Form Template has been designed to meet current regulatory, institutional and ethical standards. The SickKids REB strongly recommends that study teams use this template when creating consent forms for their study. If study teams wish to use a consent form template provided by the sponsor, they **must** ensure all of the consent form elements outlined in the Consent Form Checklist (available on the SickKids REB internal website template page) and content/sections missing from this consent template have been included. Note that the checklist and consent template outlines some consent form sections where the SickKids specific language **must** be used.

Please note that this **participant consent form** is required for all research studies with human participants. This includes where participants are children with the capacity to consent for themselves into research studies, staff as participants, and parents as participants.

**How to use this template:**

*GREY Highlighted text*: General instructions for the section. Please delete this in your final copy.

**BLUE text:** Guidance and example language. Refer to suggested or sample wording. You may revise the wording based on what your study requires.

**BLACK text:** SickKids approved template wording and/or examples that should not be altered without justification.

Specific example language for your study may not be provided in this document. If there is no template language for your specific situation, please create your own.

**When writing the consent, please remember to:**

* **Use plain (lay) language that is easy for a non-medical person to understand; consent forms should be written at a grade 6 reading level or below**
* Delete this instructional page and all instructional language in the template
* Avoid using “we” and “researchers” as much as possible; if used clarify if “we” and “researchers” includes sponsor
* Use a size and font of text that is consistent and easy to read (size 11 or larger is recommended)
* Define all acronyms and abbreviations when they first appear
* Use the term ‘study doctor’ when referring to physicians involved in the clinical trial, to ensure there is no confusion with the treating or primary care doctors
* Ensure that the final form is properly formatted and free of spelling or grammar errors.
* After all edits have been made, all text should be black
* If there is a possibility that participants will have capacity to consent, both a parent/surrogate decision maker and participant version of the consent form should be submitted.
* If the REB requests changes to the consent form, submit both clean and tracked changes versions of the updated consent form

**Consent to Participate in a Research Study**

**(Participant)**

**Study Title:** insert study title as written on the protocol.

If the study title is long or complicated for a lay person, a simplified version of the title may be added. This shortened title may also be used in the footer for each page of the consent form.

**Principal Investigator (Study Doctor):**

Include the name, department and contact information (i.e., telephone number) of the SickKids Principal Investigator. Indicate “Dr.” only for doctors licensed to practice in Canada; indicate “Nurse” only for nurses licensed to practice in Canada. All other Investigators should be referred by their credentials and, if applicable, country of practice.

**Example:**

**Dr. Jane Smith** Division of Neurology 416.813-####

**Co-Investigator(s):**

Include the name(s), department(s) and contact information of all SickKids Co-Investigators.

**Example:**

**John Brown, PhD** Division of Neurology, 416.813-####

**Jane Dave,** Nurse Practitioner, Division of Paediatric Medicine 416.813-####

**Study Team/Research Contact:** Include the name and telephone number of at least one research contact.

**24 Hour Contact Information:**

**(if applicable: please note the 24-hour contact should be SickKids study staff, not Sponsor contact)** If you need to get in touch with someone about the study after office hours, please contact:

Pager: (416) 123-4567

Locating Number: (416) 123-4567: Please ask for the on-call doctor and let them know that you are a study participant under [PI NAME]

**Study Sponsor and/or Funder:**

*The Sponsor is the individual or institution that takes the responsibility to initiate and/or manage the research.*

***For SickKids-initiated studies****, the Sponsor should be SickKids. If funding is provided by a grant or other funding source, please provide this information as well.*

***For industry-sponsored studies:***  *the Sponsor and funder is usually the same company.*

* Enter the full name of all sponsor(s) as documented on the protocol and/or application form, including funding sources and any drug suppliers.
* For Funded Studies: Include the name of the funding body(ies). This includes internally funded sources and in-kind support (e.g., Equipment and Supplies).

**Conflict of Interest:**

*Describe any conflict of interest that exists or may appear to exist as it relates to any of the investigators, study staff or member of their immediate family. A conflict of interest exists if there is a potential benefit to the investigator(s), study staff or member of their immediate family beyond the professional benefit from academic achievement or presentation of the results. Examples include, but are not limited to, speaker’s fees, travel assistance, consultant fees, honoraria, gifts, and intellectual property rights such as patents. A declaration of conflict of interest should include the identity of the person with the conflict of interest, the type of incentive or inducement, and its source.*

If there are no conflicts, state:

There are no conflicts of interest to declare related to this study.

If a conflict exists, see below example language

Dr. X, declares that he/she (may/will) gain financially by being involved in this study because he/she will be paid by [sponsor (insert name of sponsor)] for his/her time and effort during the study. This may create a competing interest or conflict of interest.

**OR**

As a result of his/her participation in this study, Dr. X has received (or may receive) one or more of the following benefits [from sponsor(s) (insert name of sponsor)] (speaker's fees, travel assistance, industry-initiated research grants, investigator-initiated research grants, consultant fees, honoraria, gifts, intellectual property rights such as patents, etc.). This may create a competing interest or conflict of interest.

**OR**

The spouse of Dr. X owns shares in the company [insert name of company/sponsor] that is sponsoring the study and may benefit financially if the outcome of the study shows that the product helps patients. This may create a competing interest or conflict of interest.

**Introduction**

*Throughout this form, “we” represents the SickKids researchers.*

You are being invited to take part in a clinical trial. Clinical trials are research studies that test ways to detect, treat, or manage a medical condition and to see if new treatments or new ways to diagnose diseases work and/or are safe.

This consent form describes the research study and what it means to participate. This consent form may have words that you do not understand. Please ask the study team to explain anything that you do not understand. Please take as much time as you need to think about your decision to participate or not, and ask any questions you have. If it is helpful to you, you are encouraged to discuss the study with family, friends, your personal physician, other health professionals, or any members of your community that you trust.

All participation in a research study is voluntary and you are not under any obligation to participate.

**Why am I being asked to participate?**

*Explain why the child is being asked to participate and how the participation/intervention in this study relates to standard of care/usual treatment the participant is currently receiving. Provide a brief description of the disease condition in lay terminology.*

You are being invited to participate in this study because you have [explain the main features of the population to which the research applies. See below examples of suggested wording]*.* Sample wording based on the minimum main inclusion criteria:

1. ***Main Inclusion is a disease condition:***

* *you have complex medical care needs*
* *you have been recently diagnosed to have a relapse of your cancer*

1. ***Main Inclusion is a disease and scheduled procedure:***

* *you have drug resistant epilepsy (DRE) and are being considered for a surgical procedure to treat your epilepsy..*
* *you have cystic fibrosis (CF) and are scheduled to have a colonoscopy*

1. ***Main inclusion is admission or routine clinical visit:***

* *you were recently seen at the emergency department for a suicidal attempt.*
* *you are receiving follow-up care at SickKids for your congenital heart disease.*

1. ***Main Inclusion is diagnosis, participation in an observational study/registry:***

* *you have cystic fibrosis (CF) and are participating in the Cystic Fibrosis Registry*
* *you have XLMTM and are currently part of the INCEPTUS study*

1. ***Child is a being recruited as a healthy control:*** *you are healthy and are eligible to participate in this study as a healthy control.*

*Provide a brief description of the current standard of care for the child’s disease at SickKids. Please use lay terms.*

The standard of care (or usual treatment) for children with [disease condition] at SickKids includes [refer to required content and sample wording below].

If there is current treatment available:

The current standard of care (or usual care) for the treatment of children with [disease condition] includes [state current medications available] and surgical procedures [state procedure and describe what the procedure entails]

If there is no current treatment available:

There is currently no available treatment for (state condition) at this time.

Why is this study being done?

*Explain the purpose and specific goals of the research study. A clear statement that the study involves research, and the purpose of their participation is primarily to contribute to research (for example to evaluate the safety and effectiveness of the study drug/device, to evaluate a different dose or route of administration of an approved drug, etc.) rather than to their own medical treatment.* ***A clinical equipoise statement*** *to state the unknown i.e. don’t know if the drug (study intervention) is better or worse or the same as current therapy or don’t know if this help.*

This research study is being done to [insert purpose/significance of conducting the study. E.g. evaluate the safety and effectiveness of the study drug, to evaluate a different dose or route of administration of an approved drug,].

***Clinical equipoise statement***

We don’t know if the study drug/natural health product/device/procedures is better or worse than the standard of care/usual treatment [or if standard of care/usual treatment] we don’t know if [this study drug will make you better.]

[Insert name(s) of product/agent/device] is a new type of [describe, e.g., natural health product/drug/device] for [specify condition]. Previous research has shown that it may [explain previous research results in lay terminology, e.g., [agent] has been studied in a few people and seems promising but it is not clear if it can offer better results than standard treatment.]

If you are using a drug or device that is investigational and is NOT approved by Health Canada for clinical use, state the following:

The use of [study drug or device name] in this research study is investigational. The word “investigational” means that [study drug or device name] is not approved for use by Health Canada. Health Canada is allowing the use of [study drug or device name] in this research study. Health Canada is the regulatory body that oversees the use of [natural health products/drugs/medical devices] in Canada.

If you are using a drug/device that is approved by Health Canada, but outside of the drug/device approved parameters (e.g., approved agent being used for new (not approved) condition, or being used outside of approved dosage/schedule, being used outside of approved age range, etc.), include the following:

[drug or device name] is approved by Health Canada for the treatment of [include disease/condition name]. It is not approved for use in [condition/disease name]. Health Canada is allowing the use of [study drug or device name] in this research study. Health Canada is the regulatory body that oversees the use of [natural health products/drugs/devices] in Canada

If the study involves genetic research:

*Explain the why genetic research is being done as part of this study. Refer and insert appropriate language from the Genetics Research Consent Form Language document.*

**How long will the study take?**

*State how long the participant has to do study related activities while enrolled in the study.*

Your participation in this study will be for [Insert the expected duration of participant’s participation: # of weeks, months, years)]. You will be asked to come to SickKids for # study visits. Each study visit is expected to take about [state estimated duration].

*State how long the entire study will take to complete (not the participant’s participation duration but for the clinical trial to complete) and when participants anticipate to know the results/outcome of the trial.*

The overall study should take about [total length of study in months or years] to complete and the results should be known in about [time to anticipated analysis in months or years]

**How many participants will be in this study?**

If SickKids single-centered study only:

This study is being done at SickKids only. We expect to enroll up to [#] children in this study.

If multi-centre study:

This is a multi-centre study being done in [various centres in Canada] OR [in Canada, the US and other countries worldwide]. A total of [#] children are expected to be enrolled in the study. At SickKids, up to [#] children are expected to participate in this study.

**What will happen in this research study?**

*Describe the design of the study. See suggestions below. If these suggestions are not applicable, provide a detailed description appropriate to the study protocol.*

Pilot Studies:

This research is called a “pilot study” or “feasibility study” and is done to test the study plan and to find out whether a bigger study is possible. This type of study involves a small number of participants and so it is not expected to prove safety or effectiveness. Knowledge gained from pilot or feasibility studies may be used to develop future studies that may benefit others. Participation in a pilot study does not mean that your child will be able to participate in a future larger study.

Phase I Studies (safety):

The research is being done to test the safety of a new drug [insert intervention] to see what effects it has on humans and on [insert disease/condition]. This is the first time that the Drug [Include Trade Name]/Device/Intervention is being tested in children who have (state condition). It has been tested in adults who have [state condition] before and is safe for adults to use.

OR

This research is being done to find the highest tolerated dose (or most effective dose) of a new drug called [DRUG NAME (Include Trade Name)/Device/Intervention] that can be given without causing unwanted side effects. This is the first time that the DRUG (Include Trade Name)/Device/Intervention is being tested in children. It has been tested in adults before but at a different dose, and is safe for adults to use. To find the right dose for children we will give your child a dose much lower than the one given to adults. We will increase the dosage until we find the correct dose for children.

Phase 1(dose finding/escalation):

All participants are given [insert intervention] and are watched very closely to see what side effects they may have and to make sure the side effects are not severe. This is done by starting at a much lower dose than the one that is given to adults. Participants who are enrolled in the study early will get lower doses, and those later on will get higher doses of [insert intervention]. This increase of dosage is called dose finding. Dose finding continues until a dose is found that causes severe but temporary side effects. Doses higher than that will not be given. Your study doctor will tell you at which dose level you will start the study drug.

Phase II studies:

This research is being done to see what effects (good and bad) DRUG (Include Trade Name)/Device/Intervention has on [insert study population (e.g., children with disease/condition)].

Phase III studies:

This research is being done to see what effects (good and bad) DRUG (Include Trade Name)/Device/Intervention has and [state disease condition for which drug is being tested] compared to the best available or current standard treatment given for [state condition] at this time. We want to see which treatment/therapy is better.

Phase III randomized placebo controlled studies:

This research is being done to find out specify purpose, e.g., whether it is better to receive [insert name(s) of product/agent compared to standard treatments available to treat [state condition] in children. To do this, some of the participants in this study will get insert name(s) of product/agent and others will receive a placebo. A placebo is a substance that looks like the study natural health product/drug/device but does not have any active or medicinal ingredients. The placebo in this study is not intended to have any effect on your specify condition. We don't know if the new drug/product will work better than current treatment(s) you may be receiving at this time.

Phase IV studies:

This research is being done to learn more about the long-term effects (good and bad) of DRUG (Include Trade Name)/Device/Intervention on [insert disease/condition] compared to [insert comparison] to see which is better.

Extension Study:

You are near completion of the main study in which you received [insert intervention] over [list time period - e.g. ## weeks]. In this extension study, all participants will now receive [state drug name]. *List relevant additional information such as*: If you were on placebo, you will now receive the active study drug. If you were on the active study drug, you will continue on your current dose.

Randomized studies:

If you decide to participate in this study, you will be "randomized" into one of the study groups described below. Randomization means that you will be put into a study group by chance. It is like flipping a coin. You will have a [insert randomization probability e.g., 50/50; 50%; 1 in 3] chance of being placed in [either]/[any] group. Neither you, your parent, nor the study doctor can choose what group you will be in.

For double-blind:

Neither you, your parent, nor the study doctor will know which group you are in. In case of an emergency, the study doctor can find out what group you were placed in.

For single blind:

You will not know which study group you are in. In case of an emergency, the study doctor, if they do not already know, can find out what group you were placed in.

Open-label:

This is an open-label study which means that you and the study personnel will know [insert which what drug/study intervention] you are receiving.

**What is the study intervention?**

*Describe intervention by study group, including a clear identification of experimental components of the study. See suggestions below. If these suggestions are not applicable, provide a detailed description appropriate to the specific protocol.*

Suggestion for single arm studies:

If you agree to take part in this study, you will [describe the intervention, including the method of delivery of intervention (e.g., injection, oral), the frequency of intervention, and the length of time receipt of intervention takes].

Suggestion for multi-group studies (Ensure that the Group/Arm names and descriptions are consistent with the protocol)

If you are randomized to group 1, you will [describe the intervention, including the method of delivery of intervention (e.g., injection, oral), the frequency of intervention, and the length of time receipt of intervention takes].

If you are randomized to group 2, you will [describe the intervention, including the method of delivery of intervention (e.g., injection, oral), the frequency of intervention, and the length of time receipt of intervention takes].

If you are randomized to control group, you will [describe the intervention, including the method of delivery of intervention (e.g., injection, oral), the frequency of intervention, and the length of time receipt of intervention takes].

**What else do I need to know about the study intervention?**

*Include the relevant information about the intervention from the selection below*

If standard treatment is being withheld or withdrawn, inform participants of details, for example:

Normally, you would receive [identify standard treatment] for [specify condition]. If you decide to take part in this study, you [will] need to stop [state current treatment and specify time period, e.g. the entire time you are enrolled in the study].

For studies with a washout period, provide details on washout requirements, for example:

As part of this study, you will be asked to stop taking [identify washout agent] for a period of [insert washout period in weeks/months] before you begin the study intervention.

If participation in the study restricts future treatment options, inform participants of details, for example:

If you are in [identify restriction, e.g., this study; Group 1], you may not be able to receive [identify any future treatment options that participant would be excluded from] in the future.

If the study drug has the potential to make participants infertile or other possible permanent side effects:

The study drug may prevent you from having children. The study doctor will talk to you about things that you can do before starting the study drug.

If changes may be made to the dose of the study drug after the child experiences side effects:

If you have side effects while you are on this study, the study doctor may make changes to the study drug including decreasing the dose you receive or discontinuing you from the study.

**What will happen during the study visits?**

*This section should outline what the child’s participation will involve in order to comply with the study protocol. For example, the number of study visits, research procedures and testing, maintenance of diaries, completion of questionnaires, all procedures that is required and they will have to do in order to be enrolled in the study should be described below. Provide a chart outlining what happens at each visit to simplify the consent form and assist the participant in understanding what participation in the clinical investigation will involve. Do not repeat the research related procedures in words under each type of study visits.*

Example STUDY PLAN FLOW [Modify as applicable]

*If the study has a complex design where a pictorial representation of the study flow would benefit the potential participants, include a flow chart.*

The diagram below provides an overview of the study steps/procedures and the section below describes the research related procedures that you will have to do as part of this study.

**Screening Visit** assessments to see if you meet all the requirements to be in the study.

Randomization Visit/Study enrollment

**Group 2**

Study drug

length of participation

**Group 1**

Placebo Group

length of participation

**Group 3**

provide details

length of participation

In addition to receiving the study drug, follow up assessments for will be done for [insert number of weeks, months,]

**End of study or Early withdrawal** study visit

**Follow-up Visits after End of study:** state # of required visits and duration

If a screening visit/Initial Visit is required before a participant begins the study:

**Screening Visit:** In order for the study doctor to find out if it is safe for you to be part of this study, you will be asked to come to SickKids for a screening visit where the following will be done:

[Provide a numbered or bulleted list of screening procedures and describe each screening procedures. If participants will be excluded or withdrawn from the study if they do not meet the study criteria, then please provide details for the participants.]:

If procedures from the baseline visit are the same: You will be doing the same tests and procedures described in the Baseline/Screening visit.

**Follow-up Study Visits:**

If there are study procedures that will be done at each and every single visit, summarize as follows:

You will need to come to SickKids for [X] study visits that will occur at [time intervals]. Each study visit will take about xx minutes. At each study visit, the following will be done:

*List study procedures:*

If there are additional procedures that need to be done:

In addition to the regular study tests and procedures, the following will be done:

1. PK testing: if mandatory, otherwise provide information in the optional parts section
2. Any other tests/procedures: include timing (what visit), description of the test in lay terms, how long the test will take, any preparations needed specific to the test.

**Withdrawal or End of Study Visit (if applicable)**

If you are taken out of the study for any reason, including if you decide to withdraw, you will be asked to complete a final study visit to make sure you are safe. This will be scheduled as soon as possible.

During this visit, the following will be done: [describe End of Study visit procedures]

**Study Visit Schedule:**

*If there are a number of procedures and visits, it is best to describe the visits in table format. Please ensure that the terms for the study visits are consistent with the list provided above. The table in the study protocol will use technical terms so please change these to lay terms.*

Example table for multiple visits/procedures:

The chart below provides a list of the study procedures explained above and what visit the procedures will be done.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Visit | Screening | Baseline | Visit 1  [select one] Week/  Month X | Visit 2  [select one]  Week/  Month X | Visit 3 | Visit 4 | Visit 5-8 | End of Study Visit | Follow-up Visit |
| Length of visit | 2 hours | 90 minutes | 30 minutes | 1 hour |  |  |  |  |  |
| Informed consent |  |  |  |  |  |  |  |  |  |
| Review of Medical records |  |  |  |  |  |  |  |  |  |
| Randomization |  |  |  |  |  |  |  |  |  |
| Start Study Drug |  |  |  |  |  |  |  |  |  |
| Physical examination |  |  |  |  |  |  |  |  |  |
| A row for each type of imaging |  |  |  |  |  |  |  |  |  |
| Blood tests |  |  |  |  |  |  |  |  |  |
| Pregnancy test (if applicable) |  |  |  |  |  |  |  |  |  |
| Questionnaires |  |  |  |  |  |  |  |  |  |
| Diary |  |  |  |  |  |  |  |  |  |
| Add rows for each procedure |  |  |  |  |  |  |  |  |  |

*If central review is a mandatory component of the research, include the following section. Provide a description of the material(s) being reviewed centrally, including the type, reason, location, retention and identifiers.*

Central [type of review e.g., Imaging Review (e.g. CT Scans, MRI images, etc.)] Review

[Specify material being submitted e.g., de-identified Copies of your CT scans/Surgical specimens] will be collected as part of this study. De-identified copies will be sent to [specify institution and location conducting review], where they will be [reviewed/stored], and kept until [specify retention period] when then they will be destroyed. This process is called central review and is required for [include description of rationale, e.g., quality assurance and data management].

**What other samples will be collected as part of this study and why?**

*Describe the* ***mandatory*** *sample collection, including the sample type and amount and manner/safety of acquisition, purpose of the research (including any commercial use), measures employed to protect privacy and minimize risk, and length, method, and location of storage. See suggestions below, or revise as applicable to the research.*

All the samples collected from you for this study will be de-identified by replacing your identifiable information name with a “study number”. Despite protections being in place, there is a risk of unintentional release of information. Samples will be used only for purposes of this study as explained below and will not be sold.

In addition to the samples collected as part of each study, we will be collecting the following additional biological sample(s) as part of this study:

**Tissue Collection (If applicable)**

*Describe the method of tissue sample collection. Specify the location and purpose for the review. See example text below, or revise as applicable to the research*

If a tissue sample from previous collection is required/used:

A small sample of your tissue that has already been removed by a previous surgery or biopsy [if collection time can be indicated state it here, e.g. at the time of diagnosis] will be obtained by the study team doing this study. No further surgeries or biopsies are required of you for this purpose. If applicable, explain whether they may still participate if a sample is not available or whether a fresh tissue sample will then be required – see below.

If a fresh tissue sample is required

*Describe the associated risks in the risk section.*

As part of this study, you will have a tissue biopsy. A tissue biopsy is a type of surgical procedure, which will remove state how much tissue is to be taken e.g. a pea size piece of your insert tissue type e.g., liver. Explain in lay language whether this will be done using a local or general anesthetic and whether overnight hospital stay may be required.

**Blood/Urine/list other samples Collection** **(If applicable)**

*Describe the method of blood/urine/other sample collection. See example text below, or revise as applicable to the research*

Blood samples will be taken by inserting a needle into a vein in your arm. These will be taken at the same time as your clinic related tests whenever possible. [Specify amount of blood to be collected in ml and teaspoon/tablespoons. Describe use of local anesthesia (all research blood draws should offer local analgesia).] These blood samples will be analyzed at SickKids OR sent to an external laboratory for analysis

Urine will be collected Specify number of samples to be collected and timing (e.g., specify if 24-hour collection) if multiple samples are required. These urine samples will be analyzed at SickKids OR sent to an external laboratory for analysis.

**Other samples Collection** **(If applicable)**

*Describe the method of other sample collection and the associated risks in the risk section.*

Identify location where specimens will be retained. For example:

Central Review of Biological samples

*List the samples that will be sent for central review and why.*

The [specify sample type] will be sent to a laboratory in [insert name, location] where they will be examined for [insert purpose or type of testing; include description of rationale].

**If samples are collected for secondary/exploratory purposes (e.g. genetic research, or biomarker research) review the section below and include necessary information as applicable:**

**What type of testing will be done on the samples collected as part of this study?**

*List complex type of testing that will be done on the samples collected, such as genetic, pharmacokinetic, pharmacodynamic testing or testing that are done to meet the study objectives.*

If the study involves genetic research:

*Insert appropriate language from the Genetics Research Consent Form Language document.*

Specify what will happen to samples once the mandatory research has been completed.

If leftover samples will be destroyed once the mandatory research testing has been completed:

Once the tests required for the study have been completed, any leftover samples will be [specify what will happen to samples: e.g. stored for ## for re-testing purposes and destroyed after ## years or will be destroyed by insert whom].

Describe who will be informed of the results of the mandatory research. For example:

Reports about any research tests done with your samples will not be given to you, the study doctor(s) or study staff, your doctor, or other health care provider(s). These reports will not be put in your medical records.

Or

Reports about research tests done with your samples will be given to the study doctor(s). If you would like to learn the results of this research, please let them know.

**What are the risks, harms or discomforts of the study?**

*The informed consent process must describe the reasonably foreseeable risks or discomforts to the subject. This includes risks or discomforts of tests, interventions and procedures required by the protocol (including standard medical procedures, exams and tests), especially those that carry significant risk of morbidity or mortality. Possible risks or discomforts due to changes to a participant’s medical care (e.g., by changing the subject’s stable medication regimen or by randomizing to placebo) should also be addressed.*

You may experience side effects from participating in this study. Some side effects are known and are listed below, but there may be other side effects that are not known or expected. You should tell the study doctor if you have any complaints, behavior changes, changes to your health, or had other doctor visits or hospitalizations outside of the study visits. It is important that you discuss these with the study doctor.

Risks and side effects related to the experimental study drug, [insert name of product/agent/device], include:

***Nature of risks to include:***  *Describe all reasonably foreseeable risks, harms, or discomforts. Include both physical and psychological/emotional risks as applicable to the research; do not include risks from standard clinical care unless specifically increased in the research setting.*

***Language:*** *Include lay language explanation of any side effects;*

***Categorization:*** *When detailed information about the side effect profile for the intervention is known, categorize risks by frequency. Examples of these categories are provided below - other categorizations may be used depending on the presentation of risks in the Investigator Brochure/Product Monograph;*

***Information to provide****: address frequency, severity, and long term impact or reversibility. When applicable, specific symptoms for serious side effects of which the participant should be aware (e.g., in order to seek immediate medical assistance) should be included*

Suggested categories (may be presented in list or table format):

Very likely (21% -100%: more than 21 out of every 100 participants):

Less likely (5 – 20%: 5-20 out of every 100 participants):

Rarely (1 – 4%: 1 to 4 out of every 100 participants):

[Below is a sample of a table that may be used. The category percentages are a guideline and may be modified as appropriate.]

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Side Effect | Frequency | | | | Severity | | | Long Term Impact | |
| Very Likely  (30-100%) | Likely  (10-30%) | Less Likely  (1-10%) | Rare  (0-1%) | Mild | Moderate | Severe | Temporary | Permanent |
| XXXX |  | X |  |  |  | X |  | X |  |
| YYYY | X |  |  |  |  |  | X | X |  |

When limited numbers of individuals have been exposed to the intervention and the risks cannot accurately be quantified, the following language should be included (if applicable):

As of insert date, specify number people have been given this intervention and the side effects that have been reported are:

* Specify number experienced specify side effect e.g., headaches

If Phase I and side effects in humans are unknown:

Insert name of product/agent/device is in an early phase of development and so the side-effects in humans are unknown at this time. Animal studies to date show [list using lay language].

If study is **stopping** standard of care treatment, include the following:

The risks and side effects of stopping standard or usual treatment include [state…]

*If the study drug will be used in combination with standard treatment, include the following*:

As part of this research, you will be taking the study drug in addition to the usual treatment prescribed by their treating doctor. There is a chance that this combination could change the side effects or the effectiveness of the medicine(s) you are currently taking. This could mean that you could experience more side effects than you would with the standard treatment alone. It could also mean that your current treatment may not work as expected.

It is possible that other medicines that you may be taking (such as medicines prescribed by your treating doctor) and over-the-counter medicines (like vitamins, or herbals) may interact with the study drug. This may cause the study drug to not work as expected or result in severe side effects. Make sure you tell the study doctor about all the drugs, vitamins, or herbals that you are taking.

Interactions/Contraindications with Contraception Methods. If applicable, insert:

The study drug/devices/procedures may interact with [describe known interactions or contraindications with specific contraception methods]

If participation in this study puts the participants at increased risk of long-term effects, include the following:

Long term effects of the specify test/intervention used in this study include an increased risk of developing [specify long-term risk e.g., cancer].

If the study involves radiation risk, it must be stated within the main consent form and adhere to the template language below.

**Potential Radiation Risk Language for all Research studies involving research-specific radiation (above that is required for standard of care) (If applicable):** *Insert this section and the language below when there is radiation exposure due to research procedures, regardless of dose*:

The radiation risks explained below are from ionizing radiation used for x-rays or other imaging such as CT scans. Standard care often involves the uses of x-rays or other scans that use ionizing radiation. The information below explains any extra risks from additional x-rays or other scans that are only required as part of the research study. The risk of this radiation is dependent on many factors such as your age, body, medical history, area of imaging and procedure type. Studies have shown that exposure to ionizing radiation may cause damage to your genetic makeup (DNA) and increase the risk of cancer. The average effective dose from natural background radiation in Canada is 1.8 mSv per year, ranging from 1.3 mSv/y (Vancouver) to 4.1 mSv/y (Winnipeg). You can talk to your study doctor about these risks and whether there are other imaging options available.

Insert language below when the radiation dose less than 3 mSv:

The amount of radiation you may be exposed to from research procedure(s) in this study is/are less than 3 mSV. This dose is within the range of background radiation for 1 year in Canada.

OR

Insert language below when the radiation dose participants will be exposed in this research study is between 3 mSV and 30 mSV.

The amount of radiation you will be exposed to from research procedures in this study are <# mSv and ## mSv <refer to the SickKids Radiation Exposure Assessment Form>. The estimated additional risk from this radiation exposure is thought to be very low/low <refer to the SickKids Radiation Exposure Assessment Form.>

The potential risks of radiation exposure in children are higher than in adults because children appear to be more sensitive to ionizing radiation and because children have longer time to experience the harms from radiation, such as developing cancer.

The life time risk of getting cancer from this study exposure is “1 in #####” <refer to the SickKids Radiation Exposure Assessment Form.> About 1 in 2 Canadians will develop cancer in their lifetimes.

The increased risk of health effects from the additional radiation exposures in the range of those you will receive while participating in this research study is small.

OR

Insert language below for ONCOLOGY patients when the radiation dose participants will be exposed in this research study is between 3 mSV and 30 mSV

The amount of radiation you will be exposed to from research procedures are <# mSv and ## mSv <refer to the SickKids Radiation Exposure Assessment Form>. The estimated additional risk from this radiation exposure is thought to be very low/low <refer to the SickKids Radiation Exposure Assessment Form.>

The potential risks of radiation exposure in children are higher than in adults because children appear to be more sensitive to ionizing radiation and because children have longer time to experience the harms from radiation, such as developing cancer. In patients who are already being treated for cancer, it is difficult to quantify the additional risk from radiation exposure from X-rays or other scans. However, the extra risk of health effects from the additional radiation exposure as a result of your involvement in this research study is small.

If the radiation dose exposure in a research study is greater than 30mSv, **additional language may be requested to be included in the consent form upon REB review.**

If the study involves genetic research:

*Insert appropriate risk language from the Genetics Research Consent Form Language document.*

*List the risks from most severe to least severe. For example, potential risks of radiation and genetic research is more severe than risks associated with* [*blood draw.*](http://my.sickkids.ca/research/clinical-research-services/Documents/Ethics%20Documents/REB%20Blood%20volume%20guidelines%20-%2014Jul2017%20(4).docx)

Privacy Risk

Even though the risk of identifying your child from the study data is very small, it can never be completely eliminated.

**Are there reproductive risks? (if applicable)**

*If there are any reproductive or pregnancy-related risks, you* ***must*** *use the following language. Language from sponsor is not accepted. Please remember, this is section should provide information about known and unknown reproductive risk related to the use of a study drug or device. It is not a section for listing contraceptive methods. Discussion about contraception should be part of the separate discussion with the child’s treating physician or study doctor. The consent form should be kept general. Do not deviate from the provided template language below.*

Insert the following pregnancy risks if effect of the study drug on unborn child is unknown:

Pregnant or nursing women are not eligible to participate in this study. It is unknown what effect these treatments may have on an unborn child. For this reason if you are of childbearing age, your study doctor will discuss safe contraceptive methods with you to ensure that you do not become pregnant or father a baby while taking the study drug and ## days/months/years after.

What if the participant becomes pregnant during the study? Explain the following:

If you become pregnant during the study or if you father a baby during the study, the study doctor should be notified immediately.

If it is known that the study drug is known or suspected to be harmful to an unborn baby:

The study drug is known (or suspected) to be harmful to an unborn child.

You must not become pregnant or father a baby while on this study and for [##] months afterwards because the study drug(s) or procedures used in this study might be harmful to an unborn child. Your study doctor will discuss safe contraceptive methods with you to ensure that you do not become pregnant or father a baby while taking the study drug and ## days/months/years after.

If you are able to get pregnant, a [insert type blood/urine] pregnancy test will be done. The results of the pregnancy test are confidential and a doctor or a nurse will explain the results of the test to you in private.

Privacy laws mandate that the pregnant woman be told in confidence that she is pregnant, and appropriate supportive counseling should be offered at the same time. It is the pregnant woman’s choice to reveal the pregnancy to their family and the duty of the physician is to support them in any decision they make. Therefore, reasons why you cannot participate or, if enrolled, why you can’t continue to participate, may only be revealed to your parent/SDM as ‘your child’s screening reveals she cannot continue with/be part of the study’ or ‘your child’s condition no longer fulfils the criteria for the study’.

**Are there benefits from being in the study?**

*State the direct benefits, or the possibility of direct benefits, that are likely for research participants. If there is no known clinical benefit, ensure this is stated. Note that possible incidental findings are not considered a benefit.*

If there are no known direct benefits, state:

You may not benefit from being in this study. However, the information we learn from this study may be used to develop [new treatments].

Describe the generalizable or societal benefits for example:

We hope that the information learned from this study can be used in the future to benefit other people with a similar disease and/or health condition.

**What are my responsibilities in this study?**

*Identify participant responsibilities. Include, add to, or modify bullets below as applicable. Include only those relevant to your protocol. Here are some examples:*

If you choose to participate in this study, you will be expected to:

* Tell the study doctor about all of your current medical conditions.
* Tell study staff about your health since the last study visit. Any changes to your health may be related to the [study drug, study intervention, medical device inserted or procedures done as part of this study].
* Tell the study doctor about all your prescription and non-prescription medications such as over-the-counter drugs, and supplements, including vitamins and herbal medications, naturopathic treatments.
* Check with the study doctor before starting, stopping or changing any medications. This is for your safety as these may interact with [the study drug or device] that you receive while you are in this study.
* Tell the study doctor if you are thinking about participating in another research study.
* *For clinical drug trials only*: Return any unused study medication.
* *If applicable*: Tell the study doctor if you become pregnant or father a child while participating in this study
* Return any [specify medication, seizure diaries, logs or questionnaires] that you take home to complete.
* *If any food or drink is not allowed due to possible drug interactions*: Make sure that you do not eat [grapefruit] or drink [grapefruit juice] and specify what dietary restrictions are required] during this study.
* *If a washout period is required*: Make sure that you stop taking name for specify washout period.
* *For clinical drug trials only*: Insert name of study drug is for you alone, and must not be shared with others. If applicable, include: If someone accidentally takes insert name of study intervention, include instructions e.g., they should immediately go to the nearest emergency department.
* *If fasting is required prior to the study visit:* Make sure you does not eat for [state duration of fasting (i.e. 8, 10 or 12 hours) before (specify which visits require fasting).
* *If required pharmacokinetic testing:* Make sure that you do not take the study drug before [specify which visits].
* Ask your study team about anything that worries you.
* Tell the study staff if you change your mind about being in this study.

**What other choices are there?**

*Explain the alternative options applicable to the study population, and their important potential benefits and risks. Refer to suggestions below as applicable.*

You do not have to take part in this study in order to receive treatment or care. Please talk to your treating doctor about other options. Other options may include, but are not limited to:

List applicable treatments available to participants (examples below may be used as applicable).

* Standard of care/usual care
* Supportive Care. This type of care helps reduce pain, tiredness, appetite problems and other problems that may occur as part of your child’s illness. It does not treat your condition directly, but instead tries to improve how you feel. Supportive Care tries to keep you as active and comfortable as possible.
* Other research studies may be available if you do not take part in this study

Please talk to your treating doctor or the study doctor about the known benefits and risks of these other options before you decide to take part in this study.

Suggested wording for studies using healthy volunteers

You do not have to take part in this study.

If no alternative treatments exist:

You can choose not to participate in this study and continue on with your current care (i.e. Standard of care).

**What are the optional parts to this study? (if applicable)**

*In some cases, sub-studies require very complex explanations. In these cases, sub-studies should be consented to using a separate consent form. If you are unsure whether you should embed the sub-study in the main study consent form, or use a separate sub-study consent form, please contact the REO for guidance.*

If optional consent will be sought to store leftover samples for future research:

Once the tests required for the study have been completed, there may be some leftover samples. The sponsor [insert name] would like to store your left over samples for future research. Please review the information below and provide your consent for the sponsor to the use of these left over samples for future research studies explained below.

If a separate consent will be used for the optional sub-studies:

The sponsor, [insert name] and/or the researchers at SickKids doing this study are interested in doing additional optional research. You will be given another study consent form to read about this optional research. You can decide to not participate in the optional research and still participate in this main study.

*When the optional components are embedded in the main consent document, it’s important that the consent gives the participant background information on the optional component(s) and clearly indicates that it’s optional. This must be followed by the participant’s initials where the participant can clearly indicate whether or not they want to take part in the optional component(s).*

The sponsor, [insert name] and/or the researchers at SickKids doing this study are interested in doing additional optional research. This optional study is for [define purpose of sub-study].

*If more than one optional components have the general statement below, and list and explain each of the optional studies.*

The sponsor, [insert name] and/or the researchers at SickKids doing this study are interested in doing additional optional research studies. These studies are explained below.

You do not have to take part in the optional study/studies to take part in the main study.

1. Storing left over samples for future research

This optional study is for [define purpose of sub-study]. It requires [define requirements such as additional blood draws or questionnaires, how many more visits, what will be done with the collected data/biological samples].

Please initial next to your preference:

|  |  |
| --- | --- |
| Options | Initial |
| Yes, you can collect my left over <insert sample types> for the purposes of <type of research to be done>, along with my de-identified research data from this study. |  |
| No, you cannot collect my left over <insert sample types> for the purposes of <type of research to be done>, along with my de-identified research data from this study. |  |

If the optional parts involve genetic research:

*Insert appropriate language from the Genetics Research Consent Form Language document.*

2. (Additional) Genetic Research

This optional Genetic research study is done to [define purpose of sub-study]. It requires [define requirements such as additional blood draws or questionnaires, how many more visits, what will be done with the collected data/biological samples].

Please initial next to your preference:

|  |  |
| --- | --- |
| Options | Initial |
| Yes, you can collect my <insert sample types> for purposes of genetic research to do <type of research to be done>, along with my de-identified research data from this study. |  |
| No, you cannot collect my <insert sample types> for purposes of genetic research to do <type of research to be done>, along with my de-identified research data from this study. |  |

**If this research will include a request to store biological samples for future research (ex. establishment of a biobank), include the following:**

*For biobanking that will involve genetic testing, see the Genetics Research Consent Form Language document. Depending on the nature of banking, the REB may request a separate consent form for biobanking of samples for future use.*

**Request to collect and store biological samples for future research**

As part of this research study, sponsor, [insert name] and/or the researchers at SickKids would like to ask you to store your left over OR collect extra [specify the biological samples (ex. Blood sample, tissue etc.] and/or de-identified research data from this study for use in future research studies. This research could include [describe potential future research] and future unknown research studies

Sponsor, [insert name] will decide the type of research that is done on these samples and with whom they will share these samples for research purposes.

Please initial next to your preference:

|  |  |
| --- | --- |
| Options | Initial |
| Yes, you can collect my <insert sample types> to be stored in a biobank as described above for use in future unknown research studies, along with my de-identified research data from this study. |  |
| No, you cannot collect my <insert sample types> to be stored in a biobank as described above for use in future unknown research studies, along with my de-identified research data from this study. |  |
| Yes, I agree for my <insert sample types> collected in this study to be used for research purposes with commercial companies. |  |
| No, I do not agree for my <insert sample types> collected in this study to be used for research purposes with commercial companies. |  |

Photographs

Providing photographs for research purposes is not mandatory. All personal health information will be removed from photographs. All efforts will be made to blur or remove identifiable physical marks like unique birth marks, tattoos and pictures of your skin on your face, from the clinical photographs of your skin. However, there is still a risk that you may still be identified from these images.

Please initial next to your preference:

|  |  |
| --- | --- |
| Options: | Initials |
| I **allow** the use of any photos which are part of my medical file, **including any photos of my face,** **identifiable physical marks such as birth marks, moles, and/or tattoos.** I understand that these pictures will be sent to the <insert with whom the images will be shared.> |  |
| I **allow** the use of any photos which are part of my medical file, **excluding any photos of my face.**  I understand that these pictures will be sent to the <insert with whom the images will be shared.> |  |
| I **do not allow** the use of any of my images |  |

We will ask you for your consent before any identifiable images of you are used in publications. You may choose to withdraw your photographs at any point during the study.

Audio: Will parts of their interview be included in presentations or publications or in any other form of dissemination of results?

We may decide to use parts of the transcription without your name and voice in presentations or publications in the format of quotations. You have the option to refuse your participation in this research study. Please initial next to your preference:

|  |  |
| --- | --- |
| Options | Initials |
| I **allow** the use of parts of my de-identified transcription in presentations and publications. |  |
| I **do not** allow the use of parts of my de-identified transcription in presentations and publications. |  |

If the study involves genetic research:

*Insert appropriate language from the Genetic Research Consent Form Language document.*

**Can I choose to leave the study?**

It is your choice to decide to take part in this study, and participation is voluntary. You can change your mind at any time during the research study. You may have to come to SickKids for a ‘withdrawal visit’ assessment to make sure it is safe for you to stop the study drug. [Insert details about what they have to do withdrawal visit, or refer to study visit schedule].

The study team may ask why you are withdrawing for reporting purposes, but you do not need to give a reason to withdraw from the study if you do not want to. Withdrawal from the study will not have any effect on the care you or your family will receive at SickKids. If you decide to leave the study, you can contact a member of the study team to let them know.

***Note:*** *Requiring a written notification constitutes an additional burden to the parent/participant and is not acceptable. It is the study team’s responsibility to document the request. Verbal notification is sufficient.*

**Can I withdraw my samples from the research study? (if applicable)**

If you no longer want your samples to be used in this research you can request to have your samples withdrawn and destroyed. Please note that any samples that have been shared cannot be withdrawn.

*If samples were collected as part of the mandatory main study:*

Biological samples <insert types of samples> collected as part of the main study can be withdrawn <explain how and when>

Describe any limits of the withdrawal, if applicable. For example:

Biological samples [insert types of samples] collected as part of the main study cannot be withdrawn because [explain why samples cannot be withdrawn].

If samples were collected as part of the optional part:

Biological samples [insert types of samples] collected as part of the optional study can be withdrawn [explain how and when].

Describe any limits of the withdrawal, if applicable. For example:

Biological samples [insert types of samples] collected as part of the optional study cannot be withdrawn [explain how and when].

If the samples collected from you are made anonymous by removing the study number that is assigned to your samples, it will not be possible to identify your sample and therefore samples cannot be withdrawn and destroyed.

**Can I withdraw my research data from the research study? (if applicable)**

If you no longer want your study information to be used in this research you can request your data to be withdrawn and destroyed. Please note that any study that has been included as part of the analysis or that have been shared cannot be withdrawn.

For clinical trials with regulatory oversight, include the following

Information that was collected before you withdrew will be used for the purposes of this study and used for analysis cannot be withdrawn, but no new information will be collected after you withdraw from the study.

OR If the participant can withdraw information collected prior to withdrawal

If you want to leave the study and want to withdraw your de-identified information collected for the research study, let a member of the study team know.

**What if the researchers discover something about me? (if applicable)**

*If incidental findings are anticipated as a result of the study, include the following section and address what information will be provided to participant.*

**Genetic Incidental findings (if applicable):**

[*See Genetics Research Consent Form Language – language from this document must be inserted here*](http://my.sickkids.ca/research/clinical-research-services/Documents/Ethics%20Documents/Genetic%20Consent%20Language%20April%2023%202018.docx)*.*

If there is potential for medically actionable secondary findings from research study procedures:

During the study, the researchers may learn something about you that they didn’t expect. For example, the researchers may find out that you have another medical condition from imaging, lab results and or genetic testing. These types of findings are called secondary findings or incidental findings. Some secondary findings may be **medically actionable.** Medically actionable secondary findings mean there is a high chance of a health problem AND treatment and/or screening is available for this health problem.

If any new clinically important information about your health or medically actionable information are obtained as a result of your participation in this study, we will let you know. We will only talk to you about those medically actionable findings that we think are likely to have a major effect on health. Seeing a medical specialist could be helpful as there might be specific health recommendations for you and/or family member(s). We will work with you, your family and your doctor(s) during this process.

**Example- Incidental Findings Language for studies involving imaging:**

The MRI scan being done is designed to answer research questions, not to examine your brain for medical analysis. This research MRI scan is not a substitute for one that a doctor would order, and it may not show problems that would be picked up by a medical MRI scan. A radiologist will review your scans from this research study. In the very unlikely event that abnormal findings are found,

For patient participants:

The Principal Investigator will contact your SickKids Physician about any relevant findings.

For healthy volunteers:

The Study Doctor will contact your primary care physician. In case this is necessary, you will be asked to provide your family doctor’s name and contact information. If you are being treated by a physician at SickKids, he/she will be notified of any relevant findings.

For adult participants with reportable imaging:

We will contact you to help you arrange medical follow-up to interpret the significance of the findings, if any. We may also ask a radiologist, or other health professionals, to look at your scan and by signing this consent form you agree to the release of the scan for review. It is possible that you could be unnecessarily worried if a problem were suspected, but not actually found.   
If abnormal findings are found, the Study Doctor will contact you to report these findings and recommend that you follow up with your family doctor.

**Example - Incidental Findings Language where blood test results are part of the study:**

The blood test being done is designed to answer research questions, not to examine your blood for medical purposes. This research blood test is not a substitute for one that a doctor would order, and it may not show problems that would be picked up by a clinical blood test. A research staff will review your blood test results acquired as part of this research study. In the very unlikely event that abnormal findings are found, the Study Doctor will contact your SickKids Physician about any relevant findings

**Can participation in this study end early? (if applicable)**

If the study doctor decides to withdraw you from the study:

The study doctor may take you out of the study if (list reasons based on study protocol):

* Sponsor and/or Funder end the study early
* Staying in the study would be harmful.
* Your need treatment that is not allowed in the study.
* You fail to follow study procedures.
* You become pregnant.
* The study is cancelled.
* There may be other reasons to take you out of the study that we do not know at this time.

If participant becomes lost-to-follow-up and study team on behalf of the sponsor will look for updates:

If you fail to return for scheduled visits, the SickKids study team will make several attempts to get in touch with you to see if you still want to be part of the study. If the study staff is unable to contact you, the SickKids study team will access publicly available information about you and share your de-identified health status information with the Sponsor.

**Will it cost me or my family anything to be in this study?**

*Inform the participant of any anticipated expenses or loss of income associated with participation in the clinical trial that will not be reimbursed.*

If participation could result in additional costs, include an explanation of these potential costs and why the sponsor cannot reimburse for the expense. Ensure that examples of extra costs are consistent with the research project.

Taking part in this study may result in added costs to you, such as:

*Lists the extra costs the participants may have to cover that is associated with the study.*

* Example 1

**Will I be paid and/or reimbursed if I join this study?**

*Describe any reimbursement and/or compensation provided to participants, or state if no compensation is provided.*

You will not be paid to be part of this study. If costs reimbursed: However

we will reimburse you or your parent(s) for all your reasonable out of pocket expenses, such as meals, babysitters, parking and transportation costs to and from SickKids, up to a maximum of $[state amount per study visit], for your participation in this research study. If you stop taking part in the study, we will pay you or your parent(s) for expenses you have incurred up until that point.

If no payment/reimbursement:

We do not anticipate any additional costs to you or your parent(s) for participating in this research study because <insert why they will not incur additional costs>

If a third party company will reimburse the participant:

*Provide any additional information about third party reimbursement in a separate document. Do not include the details here and elongate the consent form.*

A company called <insert company name> will manage <insert type of reimbursements, travel, expense> reimbursements. When you complete a study visit, the amount associated with that study visit expense will be <insert how they will be reimbursed>. In order for <insert company name> to be able to reimburse your parent/SDM, they will have to provide the following required information about themselves: their full name, birth date, full address, and contact details (phone number(s) and or email address). Your name and anything that can identify your will not be shared with the Sponsor of the study.

If compensated:

As a token of appreciation, you will be given $XX <if providing gift card, provide category of stores or specific store name> for your participation in this study.

*If there are multiple visits, and compensation for time will be given to the child at each visit:*

As a token of appreciation, you will be given a $XX <if providing gift card, provide category of stores or specific store name> after each study visit.

If recognizing participation in the study:

Please note that this is recommended in addition to any compensation for time to recognize the child’s participation in the study.

In recognition of your participation, you will be given a certificate of participation and/or # volunteer hours.

It is possible that a commercial product may be developed as a result of this study. You will have no rights to any products that may be created as a result of this study or any future research studies using this research study data. You will not receive royalties from any products that may be created as a result of this study or any future research studies.

**What personal health information will be collected about me as part of this study?**

Personal health information (PHI) is any information that is collected about you from your medical records. PHI also includes any information collected from/about you during the study.

If you decide to participate in this study, the SickKids study team (study investigators, coordinators, nurses and delegates) will collect personal health information about you. This includes things learned from the study procedures described in this consent form and/or information from your medical records. The study team will only collect the information they need for this study.

If direct or indirect identifiable information will be collected as part of this study, the following should be included:

Some of the data collected for this study includes identifiable information about you, including: [list all potentially identifiable information that will be collected as part of this study. Please be sure to list all direct identifiable information that will be collected (i.e. name, OHIP Number, MRN, SIN, etc…) and all indirect identifiable information (i.e. telephone number, address, postal code, full date of birth, solid organ transplant date, etc…). This information is needed to [Include the reason for collecting this information]

If race/ethnicity information is collected as part of the study, identify this and provide a rationale. See suggested text, or modify as applicable

Studies involving humans sometimes collect information on race and ethnicity as well as other characteristics of individuals because these characteristics may influence how people respond to different interventions. Providing information on your race or ethnic origin is [voluntary/required.]

**How will my privacy be protected?**

**ONLY REVISE THE BLUE FONT SECTIONS***.* ***Note:*** *If there will be disclosure of personal identifiers, i.e., disclosed on any research-related information/documents including samples or scans, or as part of the unique identifier, these disclosures must be justified in the REB application and approved. Please ensure that you are aware of institutional and REB policies with respect to the disclosure of personal identifiers. The REB strongly recommends that you have this reviewed by your external sponsor prior to submitting the consent form to the REB.*

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

We will respect your privacy. The (Sponsor/Funding agency/Coordinating centre, NAME) is also committed to respecting your privacy. No information about you will be given to anyone or be published without your permission, unless the law requires us to do this.

Information collected about you will be “de-identified” by replacing your name with a unique participant code. Records identifying you at SickKids (including the link between your identity and your participant code) will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

The SickKids study team is in control of the study code key, which is needed to connect your personal health information/personal information to them. The link between the study number and your identity will be safeguarded by the SickKids study staff and will not be available to the (Sponsor/Funding agency/Coordinating centre). SickKids guidelines include the following:

* All information that identifies you, both paper copy and electronic information, will be kept confidential and stored and locked in a secure place that only the study staff will be able to access.
* Electronic files will be stored securely on hospital or institutional networks or securely on any portable electronic devices.
* No information identifying you will be allowed off site in any form without your consent. Examples include your hospital or clinic charts, copies of any part of your charts, or notes made from your charts.

The following people may look at your original (identifiable) medical/study records to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines:

Include only those organizations requiring permission for direct access to participant medical records containing identifying information (e.g., permission to conduct on-site monitoring/auditing). Include a brief description of their role in the research. See suggestions below, or modify as applicable to the research:

* Sponsor Name, the company that makes the DRUG (including trade name) / INTERVENTION}, and its representatives and partner companies;
* Representatives of SickKids Research Ethics Board and other SickKids staff who oversee the conduct of research at SickKids;
* Representatives of Health Canada, group of people who oversee the use of drugs in research in Canada, and (if applicable) other regulatory bodies such as the United States Food and Drug Administration (FDA).

Access to your personal health information will take place under the supervision of the Study Doctor. You have the right to access, review and request changes to your personal health information.

The study staff and the others listed above will keep the information they see or receive about you confidential, to the extent permitted by applicable laws. Even though the risk of identifying you from the study data is very small, it can never be completely eliminated.

The study staff will keep any personal health information about you in a secure and confidential location for (# of years) years as per Health Canada requirements, sponsor, publishing journal or <insert as per whom> and then destroy it according to SickKids policy.

If email will be used for study purposes (e.g., distribution of questionnaires, etc.), please add:

Communication via e-mail is not absolutely secure. We do not recommend that you communicate sensitive personal information via e-mail.

When the results of this study are published, your identity will not be disclosed. You have the right to be informed of the results of this study once the entire study is complete.

If potentially identifiable data will be sent outside of SickKids:

This study requires the transfer of identifiable study data to insert name of institution/individualfor the purposes of specify purpose. The following information will be transferred:

Include what potentially identifiable information will be collected:

* genetic sequencing results
* sensitive information about HIV or treatment for drug or alcohol abuse or mental health problems.

If de-identified/coded study data will be shared outside of SickKids, include the following:

De-identified study data will be transferred to [the sponsor; local/national/international research collaborators/industry partners]. Study data is being shared so that [explain reason for data transfer].

<If data will not be shared outside of SickKids, please ensure that this is explicitly stated>

For studies using smartphones, apps or applicable technology, describe any limits to the confidentiality. For example:

Data collected using the insert app/tool/device name resides on the insert name e.g., Apple servers and no assurance can be made about its confidentiality or that it will only be used for research purposes.

If the study involves genetic research:

*Insert appropriate language from the* [Genetics Research Consent Form Language document.](http://my.sickkids.ca/research/clinical-research-services/Documents/Ethics%20Documents/Genetic%20Consent%20Language%20April%2023%202018.docx)

If data or samples will be sent outside of Canada:

Any information and/or samples, sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries dealing with protection of information may not be as strict as in Canada. Any information and/or samples will be transferred in compliance with all relevant Canadian privacy laws.

You also have the right to request for your child’s study information to be sent to you and/or another person such as your child’s treating doctor, a member of your child’s health care team, or a family member. You can choose the way by which this information is requested. For example, you can have the information sent to you or any person you wish to have this information sent in paper or electronic format.

In some cases, your rights to your child’s information may be limited by current rules and laws related to the use and storage of information collected as part of a research study. This will be explained to you as needed.

If you have any concerns about the way your child’s information is being kept private, you can contact the SickKids Research Ethics Board or the SickKids Privacy Office.

*Note: The REB recommends noting research participation in charts only when participation may affect care, or if participants are likely to be approached for multiple research studies If participants are not SickKids patients, this section is not applicable. For clinical drug trials, medical device studies, and other interventions that may affect current the child’s treatment options, participation in the study should be noted in the child’s SickKids medical records*

Your participation in this study will be noted in their hospital or clinic chart. This is done to ensure your safety so that all their treating physician(s) will know that you are participating in a clinical trial.

Include for US FDA-regulated studies (as per 21 CFR 312.68 and 21 CFR 812.145

Because this study also falls under U.S. regulations, in the event of an investigation of the study, the US Food and Drug Administration (US FDA) may need to copy and take away records that contain your personal information. If possible, the study doctor will inform you and confirm your consent at that time. By signing this consent form you are agreeing to this release of information. You should be aware that privacy protections may differ in other countries.

General Data Protection Regulation (GDPR) language:

*If study data is being shared with any research partners or collaborators in Europe, the following language is required.* **DO NOT REVISE CONTENT.**

If your personal health information is shared with any research partners or collaborators in any country under the European Union (EU) and European Economic Area (EEA), your information will be protected by the General Data Protection Regulation (GDPR). This is a European Union law that provides protection for data and privacy of all persons in the EU and EEA. If the sponsor’s head office is in Europe: The sponsor’s head office is located in Europe and is therefore governed under GDPR. Under this law, you will retain the right to access and correct your personal data. You have the right to restrict the ways in which this information is processed and used. You may also request your information to be removed from the study. However, any information that has already been shared or made part of an analysis cannot be removed. In addition, if the information is related to safety during the study, it will need to be kept by the Sponsor. For any changes to the way your data is used, just let the study staff at SickKids know and they will inform the study sponsor.

**Will the study require any of my health care providers to share my personal health information with the researchers of this study? (if applicable)**

*If the study protocol requires that the researchers must obtain information from other health care providers, then this section should be included.*

As a part of this research study, the study doctor(s) may ask to see your health care records from your other health care providers. We will obtain this information from you by asking for a list of all the health care providers involved with your care and your permission for them to release information to us by signing a medical release form. The collection of medical history information from your other care providers is important in this study because [provide rationale]

**Will information about this study be available online? (if applicable)**

*For US FDA-regulated studies (Do NOT modify text) and other studies on Clinicaltrials.gov*

A description of this clinical trial will be available on <http://www.clinicaltrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

*OR*

*All other studies:*

A description of this study will be available on *insert web address*. This website will not include information that can identify you. You can search this website at any time.

**What if I am injured during/in this study?**

*If physical or mental harm is a potential harm as a result of study participation, the following section should be included.* **DO NOT REVISE THIS SECTION***.*

If you suffer an injury from participation in this study, medical care will be provided to you in the same manner that you would ordinarily obtain any other medical treatment. In no way does signing this consent form waive your legal rights or release the study doctor(s), sponsors or involved institutions from their legal and professional responsibilities.

If you require treatment for any injuries or illness related to your participation in the study, you should contact the study doctor immediately.

**How will I be informed about new information?**

We may learn new information during the study that you may need to know. We may also learn about things that might make you want to stop participating in the study. If this happens, you will be notified about any new information in a timely manner. You may also be asked to sign a new consent form that describes these new findings if you decide to continue in the research study.

**What happens after completion of the study? (if applicable)**

***Required information for clinical drug trials:*** *Participants should be given information about continuing access to the study drug after study participation ends****.***

If participants will NOT be able to continue to receive the study intervention:

You may/will not be able to receive the study intervention after your participation in the study is completed.

There are several possible reasons for this, some of which are:

* The intervention may not turn out to be effective or safe.
* The intervention may not be approved for use in Canada.
* Your caregivers may not feel it is the best option for you.
* The intervention, even if approved in Canada, may not be available free of charge, may be too expensive and insurance coverage may not be available

The study doctor will talk to you about the options.

If participants will be able to continue to receive the intervention after the study is finished.

After the study is completed, if the study doctor feels that you are benefiting from the study drug, you will continue to be provided with [insert name(s) of product/agent/device]

The study doctor will discuss all future treatment options with you at the end of the study.

**Will I receive study results?**

Research results will be shared through [journal publications, academic conferences, any other means of disseminating information]. When the results of this study are shared, your identity will not be disclosed. You have the right to be informed of the results of this study once the entire study is complete.

Explain how the participant can obtain or will be informed of the results, for example:

If you would like to be informed of the results of this study, please let the study doctor know.

*or*, if the results will be publically available in the Clinical Trial Registry or on a study website/newsletter:

The results of this study will be available on the clinical trial registry [provide information on registry]

*Or* The results of the study will be available [time] from [Principal Investigator or web site, etc.].

***Explain the format in which results will be provided:***

You will only be provided with overall study results (aggregate results from all participants). This means you will not know the results as they relate to you specifically.

*Or*

We will provide you with the overall study results (aggregated results from all participants). We will also provide you with personal results that relate specifically to you [explain what personal-level information will be provided].

**What are my rights when participating in a research study?**

You have the right to receive all information that could help you make a decision about participating in this study. You also have the right to ask questions about this study at any time and to have them answered to your satisfaction. Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form, you do not give up any of your legal rights against the study doctor, sponsor or involved institutions for compensation, nor does this form relieve the study doctor, sponsor or their agents of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to your participating in this study.

**We may do future related research studies and want to know if we can contact you about these studies in the future. Please initial next to your preference:**

|  |  |
| --- | --- |
| Initial | Options: |
| \_\_\_\_\_\_\_\_ | **Yes**, you can contact me regarding future related research studies. |
| \_\_\_\_\_\_\_\_ | **No**, I do not want you to contact me regarding future related research studies. |

**Who can I call if I have questions about the study?**

If you have any questions during your participation in this research study you can contact the Study Doctor, [PI NAME] at 416-813-#### or [specify study contact if there is one OR any research team member listed at the beginning of this consent form].

**Research Ethics Board Contact information**

**DO NOT REVISE CONTENT.** *Note that you should not state that the study has been “approved” by the SickKids REB.*

The study protocol and consent form have been reviewed by the SickKids Research Ethics Board (REB). If you have any questions regarding your child’s rights as a research participant, you may contact the Office of the Research Ethics Board at 416-813-8279 during business hours.

**Consent to Participate in a Research Study**

**Study Title:** add study title

**By signing this research consent form, I understand and confirm that:**

1. All of my questions have been answered,
2. I understand the information within this informed consent form,
3. I allow access to my medical records and/or biological samples as explained in this consent form,
4. I do not give up any of my legal rights by signing this consent form,
5. I understand that my family doctor/health care provider(s) will/may be informed of my participation in this study
6. I have been told I will be given a signed and dated copy of this consent form.

**I consent to participate in this study.**

|  |  |  |
| --- | --- | --- |
| Printed Name of Participant |  | Participant signature & date (DD/MMM/YYYY) |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Printed Name of person who obtained consent |  | Role of person obtaining consent |  | Signature & date (DD/MMM/YYYY) |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Printed Name of person who obtained consent |  | Role of person obtaining consent |  | Signature & date (DD/MMM/YYYY) |

If the study PI or Co-I will be present during the consent discussion:

*A section for “investigator signature” (example below) must be added* ***if required by the sponsor****, but this should not replace the line for the “person obtaining consent”.*

**Investigator Signature**

Investigator Signature Printed name Date (DD/MMM/YY)

My signature above signifies that the study has been reviewed with the participant by me and/or by my delegated staff. My signature may have been added at a later date, as I may not have been present at the time the participant’s signature was obtained.

**If the participant was assisted during the consent process:**

*Please check the relevant box and complete the signature space below:*

⬜ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and appeared to be understood by the participant.

⬜ The person signing below acted as a translator for the participant during the consent process. Language: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name (print) |  | Signature |  | Date (DD/MMM/YY) |

**If a Witness will/may be used as part of the consent process, please include the following:**

I attest that I am not involved in the research study, I was present during the consent discussion and that the consent process was accurately explained to, and apparently understood by the participant. I confirm that the participant named above was read the information in the consent document and that the participant has agreed to take part in the research study.

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

Print Name of Witness to the consent discussion Signature of Witness and date (DD/MMM/YY)