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

**Version Date: September 2022**

The Interventional Informed Consent Form Template has been designed to meet current regulatory, institutional and ethical standards. The Holland Bloorview REB requires 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 HB REB external website) have been included.

If participants may not be able to consent for themselves, two versions of the consent form must be submitted (participant and parent/guardian). In an effort to reduce grammatical errors/changes, both versions of the consent should use “you” throughout (no “your child” language). The parent/guardian version must contain a disclaimer that “you” refers to “your child” (see sample language under “Introduction”).

**How to use this template:**

*GREY Highlighted text*: General instructions for the section

**BLUE text:** Guidance and example language.

**BLACK text:** HB 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
* 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/substitute 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 version of the updated consent form

*This template was adapted, with permission, from a combination of the SickKids REB template and the CTO template.*

**Consent to Participate in a Research Study**

**(Type of Consent (e.g., Participant Consent))**

*For studies funded or supported by a US federal funding agency (e.g., NIH, DHHS, etc.) include this summary of information as required by the US federal regulations. This summary should contain only the information that is most likely to assist a prospective participant in understanding the reason for or against participating in the research, as outlined below. Some items included in the summary section may be repeated in the subsequent consent sections if necessary to ensure the subsequent sections make sense or if the information is core to informed consent (e.g., risk of death), otherwise duplication should be avoided.*

Summary of Informed Consent Form

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

Below is a summary of information about the study. There is more information in the document (called an “informed consent form” that follows this summary. Please read the informed consent form. The research team will also talk to you about the study and you can ask any questions you may have.

**Participation in research is voluntary**. It is your choice whether you take part in this clinical trial.

Study purpose

The purpose of this trial is *provide a brief description of the primary reason why the research is being conducted, no more than 2-3 sentences.*

Duration

It is expected that study participation will last *provide expected duration.* Participants will be followed for *define period of time*.

Study Procedures

*Briefly describe the intervention(s), highlight key study procedures and, if applicable, outline procedures that may be lengthy/burdensome to participants*

This study is looking at *describe interventional group(s).* Participants will also *briefly describe key procedures e.g., study visits every X weeks during which the researchers will do some tests*. *If applicable:* You will be asked to do *describe lengthy or burdensome procedures* which may take *specify time* extra time.

Risks.

*Describe the most important risks. Consider those most probable and/or highest magnitude of harm. Key information should not include the full list of risks.*

Participation in this study may involve risks to you. These risks are described in detail in the informed consent form.

*Include the risks participants are most likely to experience. This should not include the entire ‘very likely’ or ‘likely’ category from the main consent. Researchers must review the risks and identify those that are most likely.*

The risks you are most likely to experience are:

* *Specify risk in lay language with expected frequency*

*If applicable, include any serious risks. For the purposes of this summary, serious risks are considered those that may result in death, hospitalization, or are permanent.*

The most serious risks are:

* *Specify risk in lay language with expected frequency*

Benefits.

*Insert direct benefit, or state if there is no direct benefit. If direct benefit to participant is unknown but there is a greater benefit to society, include for example:*

We do not know if you will receive medical benefit from participation but researchers hope that this study will fulfil its purpose and benefit others in future.

Alternatives.

You do not have to participate in this study to receive medical care.

*If applicable:* You may have other medical options – you should discuss this with your health care provider.

**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 should be added. This shortened title may also be used in the footer for each page of the consent form.

**Principal Investigator:**

Include the name, and contact information (i.e., telephone number) of the BRI Principal Investigator. Indicate “Dr.” only for doctors licensed to practice in Canada (Restricted to physicians, psychologist, dentists, chiropractors and optometrists); 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:**

Jane Smith, PhD, Bloorview Research Institute, Holland Bloorview Kids Rehabilitation Hospital Contact number 416.425.6220. ext.####

**Co-Investigator(s):**

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

If the Co-Investigators are students, list the program of study, Bloorview Research Institute affiliation and academic affiliation.

**Example:**

John Brown, PhD, Bloorview Research Institute, Holland Bloorview Kids Rehabilitation Hospital, Contact Number 416.425.6220. ext.####

Jane Dave, PhD candidate, Bloorview Research Institute, University of Toronto, Contact Number 416.425.6220. ext.####

**Study Coordinator(s)/Research Contact:** Include the name and telephone number of at least one research contact.

**24 Hour Contact Information: (if applicable)**

Pager: ###.###.####

**Study Sponsor and/or Funder (if applicable):**

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

**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. NOTE 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.*

A conflict of interest can occur when a person or group has more than one interest. In research, the people who run or work on studies must tell you if they have a conflict of interest.

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

Name of investigator, 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, Name of investigator 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 Name of researcher 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**

***Note:*** *For the parent/guardian consent, the following language must be included*

*As your child’s Substitute Decision Maker, you are being asked to provide informed consent on behalf of your child. If your child gains the capacity to consent for themself, consent will be sought from them and your consent for them will end. Throughout this form, first and second-person pronouns (e.g., “I”, “me”, “my”, “you”) means the person you are representing, “we” represents the BRI researchers.*

We would like to invite you to take part in our research study. 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 staff 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 is voluntary and you are not under any obligation to participate.

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

*Explain why the participant is being asked to participate.*

You are being invited to participate in this study because you have [explain the main features of the population to which the research applies]*.*

Why is this study being done?

*Explain the purpose and specific goals of the study (what the study hopes to find out, the reason for conducting the study). Describe the background information relevant to the study, including (if applicable) the standard of care for the population, the reason for conducting the study in lay language, and the nature of the application with Health Canada (if applicable).*

The research is being done to [insert purpose/significance of conducting the study. Insert an explanation of the problems or limitations of the current standard of care that would justify carrying out the research study (e.g. high pill burden, limited efficacy, numerous side effects, and serious side effects etc.).]

The standard of care, which means usual treatment, for [specify disease/condition] is [describe the standard treatment].

[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 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:

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

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

If Holland Bloorview only:

At Holland Bloorview, up to [#] children are expected to participate in this study.

If multi-centre study:

It is anticipated that about [# of global (worldwide) participants] people will participate in this study throughout [Canada, worldwide, etc.]. About [# of local participants] people will participate in this study at Holland Bloorview.

**How long will the study take?**

This study should take [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]

Your participation in this study will be for [Insert the expected duration of participation (# of days, weeks, months, years)]. You will be asked to come to Holland Bloorview for # study visits. Each study visit is expected to take about [state estimated duration].

**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 specific 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 you 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 you 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 [such as x,y and z] 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 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/device], or better to receive no additional intervention. To do this, some of the participants in this study will get insert name(s) of product/agent/device and others will receive a placebo (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/device or no drug/product/device (with or without the standard drug) is better than the other.

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 receive the study drug. 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 previous 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 are put into a group by chance. It is like flipping a coin. Neither you nor the study doctor/investigator can choose what group you will be in. You will have a [insert randomization probability e.g., 50/50; 50%; 1 in 3] chance of being placed in [either]/[any] group.

For double-blind:

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

For single blind:

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

Open-label:

This is an open-label study which means that both you and the study personnel will know if you receive [insert study interventions].

**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

Experimental Intervention:

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)

Group 1 (Experimental group): Standard treatment (specify drug name/regimen/ intervention) plus experimental treatment (specify drug name/regimen/intervention).

If you are randomized to this 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].

Group 2 (Non-Experimental group): Standard treatment (specify drug name/regimen /intervention)

If you are randomized to this 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 you have side effects while you are on this study, the study doctor/investigator may make changes to the 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 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/may] not receive this usual treatment for [specify time period, e,g, the entire time you are enrolled in the study].

For studies with 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.

**What are the study procedures?**

*Describe the procedures that are used in the study, including clear identification of those procedures that are experimental. It is not necessary to describe the risks associated with tests or procedures with which the participant population would already be familiar.*

Non-Experimental Procedures

The following tests will be doneas part of this study. Some of these tests may be done as part of your standard care, in which case the results may be used. Some of these tests may be done more frequently than if you were not taking part in this study and some may be done only for the purpose of the study. If the results show that you are not able to continue participating, the study doctor(s)/investigator(s) will let you know.

*List the procedures and tests. Include a lay explanation of what each test involves.*

*If there are experimental procedures or medical tests, include the following section. Any standard procedures (e.g., MRI, blood draw, etc.) that are outside of standard of care should be included in the ‘non-experimental procedures’ section – this section is for procedures that are experimental (e.g., being tested as part of the research):*

Experimental Procedures

*Explain any risks of experimental procedures and medical tests in the risk section*

The following procedures/test(s) is/are considered experimental and will only be done for participants in this study:

*List the procedures and tests. Include explanation of what each test involves and the purpose/reason/rationale for including it in the research.*

If questionnaires are a mandatory component of the research, include the following section*.*

Questionnaires: You will be asked to fill out a questionnaire [provide information about the timing of questionnaires e.g., before you begin the study and then every two weeks for a year]. The purpose of the questionnaire is [include description of purpose e.g., to understand how the study intervention and illness affects your quality of life]. Each questionnaire will take about [indicate estimated time to complete in minutes] to complete. The information you provide is for research purposes only. Some of the questions are personal. You can choose not to answer questions if you wish.

If the questions are of a sensitive nature, explain that they might experience emotional distress, explain what should they do and what type of help will be provided if this happens.

During the [questionnaires, surveys and/or the interview], you may feel anxious or become emotionally upset because some of the questions are sensitive. You can skip any questions you are uncomfortable answering, stop and take a break at any time, or stop completing the [questionnaire/survey/interview].

If your responses show that there is a serious risk of harm to yourself or others, confidentiality will be broken in order to protect you or another person. If we feel that you need urgent care as result of participating in this research study we will intervene according to routine clinical care practices.

If questionnaires include medically or psychologically relevant information, but won’t be reviewed, include the following:

Even though you may have provided health information on a questionnaire, the responses will not be reviewed by your health care team. If you want your health care team to know this information please bring it to their attention.

If participant diaries are a mandatory component of the research, include the following section. Inform the participant of the expectations associated with the participant diary

Participant Diaries:

You will be asked to keep a diary of when you identify e.g., take your study drug. Please record [identify what is being recorded e.g., the exact time of taking each dose every day]. You will be asked to return the diary to this centre.

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., Radiology/Radiotherapy/Surgical] Review

[Specify material being submitted e.g., Copies of your CT scans/Surgical specimens] will be collected as part of this study. The 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].

To protect your identity, the information that will be on your [specify material, e.g. scans/specimens] will be limited to [specify which identifiers will be on the review material(s)]. If additional personal information is also being provided to the central review location (e.g., on additional forms provided with the review materials), include a description of the information provided.

**What samples will be collected as part of this study? (if applicable)**

*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.*

If the study involves genetic research:

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

The researchers doing this study need to do tests on samples (described below) to insert simple study-specific explanation of the research purposes for all samples collected.

The collection of these samples is a necessary part of this study. Samples will be used only for these purposes. The samples will not be sold.

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

Once these tests have been completed, any leftover samples will be returned to the facility where they were obtained, if needed, or destroyed.

OR

Once these tests have been completed, there may be some leftover samples. We may ask you to consent to the use of these samples for future research. If you do not consent to their use in future research, the leftover samples will be destroyed.

If there is a possibility that a medically relevant sample will be exhausted:

If you participate in this study it is possible that there will not be enough of your tissue sample left for other testing that may need to be done in the future. Please speak to the study doctor to discuss this possibility.

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)/investigator(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)/Investigator(s). If you would like to learn the results of this research, please let them know.

**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*

A small sample of your tissue that has already been removed by a previous surgery or biopsy will be obtained by the researchers 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

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. This procedure has risks such as specify risks, e.g., blood loss, pain and rarely an infection at the biopsy site.

Identify location where specimens will be retained. For example:

These tissue samples will be sent to a laboratory at insert location where they will be examined.

Blood/Urine Collection (Required)

*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 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 sent to an external laboratory for analysis.

How will samples be identified/de-identified?

To protect your identity, the information that will be on your samples will be limited to specify which identifiers will be on the sample(s). If additional personal health information is being provided to the laboratory (e.g., on additional forms provided with the review materials), include a description of the information provided, e.g., The laboratory will also receive information containing your… )

If samples will be identified with direct identifiers:

Your samples will be labeled with direct identifiers (list identifiers, e.g., name and full date of birth). The samples must be labeled with your personal information because [explain why].

Despite protections being in place, there is a risk of unintentional release of information.

Can I withdraw these samples?

*Describe the process for withdrawal of samples, and any limitations to the withdrawal. See the suggested text below, or revise as applicable*

If you no longer want your samples to be used in this research, you should tell specify appropriate contact role, who will ensure the samples are describe what will happen to samples if participant withdraws consent, e.g., returned to the hospital from which they were obtained or destroyed.

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

If tests have already been done on your sample(s) it will not be possible to withdraw those results. However, no further testing will be done.

If samples will be made anonymous at a certain point

You can request withdrawal of your specimens until [insert expected time point], when the samples will be made anonymous. It won’t be possible to return samples after this because the researchers will not know which sample is yours.

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

*You can describe each visit in words, or you can use a table to show the visits. If there are a number of procedures and visits, it is best to describe the visits in table format, If there are only a few ‘types’ of visits and most procedures are similar at each visit, then it is best to describe the visits using a written format. Note that any procedures/tests that are occurring during the visit should have already been described above in the “What are the study procedures” section.*

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.*

Start Here

Informed Consent

Screening

Randomization

Study Drug A

1 year

Placebo Group

1 year

Study Drug B

1 year

1 year post intervention follow up

1 year post intervention follow up

1 year post intervention follow up

Example table for multiple visits/procedures: *If there are a number of procedures and visits, it is best to describe the visits in table format,*

Different sets of procedures will occur at each visit. The table below outlines what will happen at each visit.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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 |
| Length of visit | 2 hours | 90 minutes | 30 minutes | 1 hour |  |  |  |  |
| Informed consent | X |  |  |  |  |  |  |  |
| Medical history | X |  |  |  |  |  |  |  |
| Height and weight | X |  | X |  |  | X |  | X |
| Blood test | X | X |  |  |  | X |  | X |
| Pregnancy test (if applicable) | X | X |  |  |  |  |  |  |
| Physical exam |  | X |  |  | X |  | X |  |
| Questionnaire |  | X |  |  | X |  |  |  |
| Food diary |  | X |  |  |  |  | X |  |
| Study Drug/Placebo |  | X |  |  |  |  |  |  |

Example of describing study visits in words:

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

**Before You Begin the Study**

In order for the study doctor/investigator to find out if it is safe for you to be part of this study, you will be asked to come for a screening visit where the following will be done: [Describe 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.]

**Randomization Visit** [insert details of what will happen during the randomization visit, if applicable]

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

You will have X study visits that will occur at [time intervals]. At each study visit, the following will be done:

*List research activities. If any activities have not already been described above, ensure they are described here.*

**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 procedures]

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

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 discuss these with the study doctor/investigator.

Risks and side effects related to the experimental intervention, [insert name of product/agent/device], we are studying 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/Device Safety information;*

***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%):

Less likely (5 – 20%):

Rarely (1 – 4%):

[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

It is not yet known if these side effects are caused by the study intervention or how likely these side effects will be.

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

An experimental intervention is being added to the standard treatment. This combination could change the side effects or the effectiveness of the standard treatment. This could mean that you experience more side effects than you would with the standard treatment alone. It could also mean that the standard treatment does not work as expected.

If a comparison arm includes standard of care treatment/intervention alone, include the following:

The risks and side effects of the standard or usual treatment will be explained to you as part of your standard care. These risks are not included in this consent form.

It is possible that other drugs (prescription and non-prescription drugs), vitamins, or herbals can interact with the study intervention. This may cause the intervention to not work as expected or result in severe side effects. Make sure you tell the study doctor/investigator about all the drugs, vitamins, or herbals that you are taking.

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 tests or procedures involve radiation:

The radiation exposure from the [name of test/procedure] is approximately [insert ### mSV (milliseivert)]. This is the equivalent of about [insert hours/days/years of] naturally occurring radiation everyone is exposed to from space and the naturally occurring radiation. The extra lifetime risk of developing cancer from this amount of radiation is likely less than [insert probability (e.g. 1 in 500,000)].

Describe discomforts associated with common tests/procedures that are for study purposes only (i.e., not part of the participant’s normal clinical care, such as blood draws, x-rays, etc.) Risks/discomforts of procedures for the collection of samples/biospecimens must also be described.

If the study involves genetic research:

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

If there are no known harms to the participants, the following statement should be included:

There no risks or harms known for participating in this study.

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

*If there are any reproductive or pregnancy-related risks, you* ***must*** *use the following language. Templated language from sponsors is not accepted.*

The effect of the study drug on an unborn child is currently not known. OR: The study drug is known (or suspected) to be harmful to an unborn child.

If you are able to get pregnant, a [insert type blood/urine] pregnancy test will be done. If the test is positive, you will not be able to enter the study. The results of the pregnancy test will be told to you by one of the study staff in private. Every effort will be made to keep positive pregnancy test results private. These results will not be shared with your parents/guardian unless you request it.

Insert if applicable:

You must not become pregnant or father a baby while on this study [and for # months afterward] because the drugs or procedures used in this study might be harmful to an unborn baby. Your study doctor will discuss safe contraceptive methods with you to ensure that you do not become pregnant or father a baby during the study. If you do become pregnant during the study or if you father a child during the study, the study doctor should be notified immediately.

Becoming Pregnant During Study. If applicable, insert:

The risk to pregnant women and the unborn baby is unknown. If your partner becomes pregnant while you are in this study [or for# months afterward], she will be asked to sign a consent form to allow access to information on the outcome of her pregnancy. If your partner does not consent to this, it will not affect your continued involvement in the study.

Potential Loss of Ability to Conceive. If applicable, insert:

Some of the drugs used in the study may make you unable to have children in the future. Your study doctor will discuss this with you.

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]

**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:

No one knows whether or not you will benefit from this study. There may or may not be direct benefits to you from taking part in this study.

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 your 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 your current medical conditions;
* Tell the study doctor about all prescription and non-prescription medications and supplements, including vitamins and herbals, and check with the study doctor before starting, stopping or changing any of these. This is for your safety as these may interact with the intervention you receive on this study.
* Tell the study doctor if you are thinking about participating in another research study
* Return any unused study medication.
* Return any [specify e.g., diaries or questionnaires] that you take home to complete
* Tell the study doctor if you become pregnant or father a child while participating on this study
* Avoid drinking/eating specify what and for how long
* Stop taking name for specify washout period
* Insert name of study intervention 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.
* Do not eat for 12 hours before visits.
* Do not take medications before visits.
* Do not eat grapefruit or drink grapefruit juice during this study.
* Ask your study team about anything that worries you.
* Tell study staff anything about your health that has changed.
* 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.*

Suggestion for therapeutic intervention studies (modify as applicable if there is no other alternative treatment available):

You do not have to take part in this study in order to receive treatment or care. 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. 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.
* No therapy at this time
* Other research studies may be available if you do not take part in this study

Please talk to your usual doctor or the study doctor/investigator 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 a separate consent will be used for the optional sub-studies:

The researchers 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 may 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 researchers doing this study are interested in doing additional optional 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]. You can take part in the main study and not take part in the optional sub-study.

I want to take part in [XXXXX] sub-study as described above.

YES \_\_\_\_Initials NO \_\_\_\_Initials

**If this research will include a request to store biospecimens 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 biospecimens for future research**

As part of this research study, we would like to ask you to let us store your [specify the biospecimen (ex. Blood sample, tissue etc] and/or health information for use in future research studies. This research could include [describe potential future research].

Will you allow us to store the biospecimens [specify the biospecimen (ex. Blood sample, tissue etc.] we collect for this study for use in future unknown research studies*?*

**Yes**, I do want my biospecimens [specifiy the biospecimen (Blood sample, tissue etc.]

Initials to be stored in a biobank as described above for use in future unknown research studies.

**No**, I do not want my biospecimens [specifiy the biospecimen (Blood sample, tissue etc.]

Initials to be stored in a biobank as described above for use in future unknown research studies.

**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.*

If the study involves genetic research:

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

*Describe types of anticipated findings.* During the study, the researchers may learn something about you that they didn’t expect. For example, the researchers may [insert anticipated incidental findings e.g. find out that you have another medical condition.] These types of findings are called secondary findings or incidental findings.

*Describe anticipated management plan. For example:*

If any new clinically important information about your health is obtained as a result of your participation in this study, you will be given the opportunity to decide whether you wish to be told that information.

**Incidental Findings Language where imaging procedures are part of the study:**

Example 1: **Pediatric Research Patients**

The MRI scan being done is designed to answer research questions, not to examine your brain medically. This 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 acquired as part of this research study. In the very unlikely event that atypical findings are found, the Study Doctor/investigator will contact your Physician about any relevant findings and recommendations.

Example 2:**Pediatric Healthy Volunteers**

The MRI scan being done is designed to answer research questions, not to examine your brain medically. This 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 acquired as part of this research study. In the very unlikely event that atypical findings are found, the Study Doctor/investigator will contact your primary care physician. If you are being treated by a physician at Holland Bloorview, he/she will be notified of any relevant findings. In case this is necessary, you will be asked to provide your family doctor’s name and contact information.

Example 3: **Adult Patients and Adult Volunteers with Reportable Imaging (as determined through a consultation with Diagnostic Imaging)**

The MRI scan being done is designed to answer research questions, not to examine your brain medically. This 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. However, in the unlikely event that we note an atypical finding on your MRI scan, 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 atypical findings are found, the Study Doctor/investigator will contact you to report these findings and recommend that you follow up with your family doctor.

Example 4: **Adult Volunteers with Non-Reportable Imaging (as determined through a consultation with diagnostic imaging)**

The MRI scan being done is designed to answer research questions, not to examine your brain medically. This 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. In this study, the scans acquired in healthy adults are typically not read by a radiologist.

In the very unlikely event that a potential atypical finding on your MRI is noted by someone involved with running the study, your scans will be reviewed by a radiologist. If an abnormality is confirmed, the Study Doctor/investigator will contact you to report the findings.

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

*See Genetics Research Consent Form Language – language from this document must be inserted here.*

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

It is your choice to take part in this study, participation is voluntary. You can change your mind at any time during the research study. 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 Holland Bloorview. If you decide to leave the study, you can contact the Principal Investigator or a member of the study team to let them know.

***Note:*** *requiring a written notification is not acceptable. It is the study team’s responsibility to document the request. Verbal notification is sufficient. Parents/patients should not be asked to go through the additional burden of writing a letter for documentation purposes.*

For clinical trials with regulatory oversight, include the following

Information that was recorded before you withdrew will be used by the researchers for the purposes of the study, but no information will be collected or sent to the sponsor after you withdraw your permission.

OR If the participant can withdraw information collected prior to withdrawal

If you decide to leave the study, you can ask that the information that was collected about you not be used for the study. Let the study doctor/investigator know if you choose this.

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

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

The study doctor/investigator 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.
* You need treatment 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.

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

*Inform the participant of any anticipated expenses associated with participation in the clinical trial*

If participation will not result in any costs, include the following

Participation in this study will not involve any additional costs to you or your private health care insurance.

Include if the intervention is supplied for free

The [insert name(s) of product/agent/device/intervention] will be given to you at no charge while you take part in this study.

If participation could result in additional costs, include an explanation of these potential costs. Ensure that examples of extra costs are consistent with the research project

Taking part in this study may result in added costs to you. For example:

* There may be extra costs that are not covered by your medical plan. Examples of these extra costs could be medications or treatments (such as physiotherapy) to treat side effects that you may experience. If you have private health care insurance, the insurer may not pay for these added costs.
* There may be costs associated with hospital visits. For example, parking or transportation, or snacks/meals during your stay.
* You may miss work as a result of participation in this study.

**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.*

If no payment/reimbursement:

You will not be paid or reimbursed for any expenses related to being in this study.

If reimbursed:

We will reimburse you for all your reasonable out of pocket expenses, such as meals, babysitters, parking and transportation costs to and from Holland Bloorview, up to a maximum of $XX, for your participation in this research study. If you stop taking part in the study, we will pay you for expenses incurred up until that point.

If compensated:

As a token of our 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, describe when they will be compensated (e.g., two gift cards of value X, one at each visit) The REB prefers that gift cards be provided after each study visit whenever possible.*

If recognized:

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

If compensation/reimbursement exceeds $500 per year, include the following:

Federal tax law in Canada requires that research payments that exceed $500 **per year** are reported to the Canada Revenue agency when taxes are filed. Holland Bloorview will report these payments to the Canadian Revenue Agency.

If applicable:

The text below is sufficient for studies where there may be future commercialization of research findings but where commercialization is not the main intended outcome. However if there is a definite plan for commercialization or there is an industry partnership, this section will need to include more detail about the plans and industry relationship as relevant.

It is possible that a commercial product may be developed as a result of this study. You will have no rights to nor receive royalties from any products that may be created as a result of this study or any future research studies using this research study data.

**How will my privacy be protected?**

***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.*

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 made public without asking you first, unless it is required by the law.

If you agree to participate this study, the Holland Bloorview research 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. They will only collect the information they need for the study.

All personal health information or personal information collected about you will be “de-identified” by replacing your identifiable information (i.e., name) with a “study number”. The Holland Bloorview study staff are in control of the study code key, which is needed to connect your personal health information/personal information to you. The link between the study number and your identity will be safeguarded by the Holland Bloorview study staff and will not be available to the (Sponsor/Funding agency/Coordinating centre).

Holland Bloorview 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 institutionally approved networks or securely on any hospital or institutionally approved portable electronic devices.
* All information identifying you will be stored in a location that is secure and private. Examples include your hospital/clinic/research file, copies of any part of your file, notes made from your file, or video/audio recordings.

If identifiable information will also be collected as part of this study:

The study will also collect personal information that could identify you, such as:

Include what potentially identifiable information will be collected

* name,
* address,
* full date of birth,
* new or existing medical records, that includes types, dates and results of
* medical tests or procedures
* sensitive information about HIV and genetic testing, or treatment for drug or alcohol abuse or mental health problems.

Indicate how this identifiable information will be protected, used, and disclosed.

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.

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

The following people may come to the hospital to look at your personal health information to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines:

* Sponsor Name, the company that makes the DRUG (including trade name) / INTERVENTION}, and its representatives and partner companies;
* Representatives of the Holland Bloorview Research Ethics Board and/or Holland Bloorview Institutional Representatives;
* 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).

The study staff will keep any personal health information about you in a secure and confidential location for (# of years) years and then destroy it according to Holland Bloorview policy. Drug, or natural health product studies that are regulated by Health Canada require 15-year study-related record retention. There are no defined regulations or standards for other research studies (i.e., non-regulated). Holland Bloorview policy recommended standard is 7 years for non-regulated studies. However, sponsor, publishing journal or professional affiliation standards for record retention should apply when necessary.

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 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. However, all study data and/or samples, that are transferred outside of Canada will be de-identified (this means it will not contain your personal identifying information such as your name, address, medical health number or contact information). Any information will be transferred in compliance with all relevant Canadian privacy laws. By signing this consent form, you are agreeing to the disclosure of your coded information to organizations located outside of Canada.

If the patients clinic chart will be noted of their participation

Your participation in this study will be noted in your hospital or clinic chart. This is recommended to ensure your safety so that any treating physician will know that you are participating in a research study.

This is typically used for genetic/tissue sample studies

It is possible that a commercial product may be developed as a result of this study. You will have no right 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.

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.

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.*

**Will the study require any of my health care providers to share my 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 researchers 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. [Provide rationale, e.g., This is to minimize adverse events.]

**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.*

If you suffer an injury from participation in this study, medical care will be provided to you in the same manner as 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)/investigator(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/investigator 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)**

*Participants should be advised as to what will or will not happen to them after they complete the study.*

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

You may 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/investigator will talk to you about your 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/investigator feels that you are benefiting from the experimental intervention, you will continue to be provided with [insert name(s) of product/agent/device].

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

**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/investigator, sponsor or involved institutions for compensation, nor does this form relieve the study doctor/investigator, 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 participating in this 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/investigator 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 [explain what personal-level information will be provided].

**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/Investigator, [PI NAME] at 416.425.6220#### or the research team members listed at the beginning of this consent form.

**Research Ethics Board Contact information**

This study has been reviewed by the Holland Bloorview Research Ethics Board (REB). The REB is a group of people who oversee the ethical conduct of research studies. The REB is not part of the study team. If you have any questions regarding your rights as a research participant, please contact the Research Ethics Office email: [researchethicsboard@hollandbloorview.ca](mailto:researchethicsboard@hollandbloorview.ca) or at 416.425.6220 ext. 3161 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/my child’s medical records and specimens as explained in this consent form,
4. I do not give up any of my or my child’s legal rights by signing this consent form,
5. I understand that my/my child’s family doctor/health care provider 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.
7. I agree to allow the person for whom I am responsible to take part in this study.

For participant consent:

**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) |

For parent/guardian consent:

I consent on behalf of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (name of child) to participate in this study.

|  |  |  |
| --- | --- | --- |
| Printed Name of Parent/Guardian |  | Parent/guardian 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:

*As well, a signatory line for “investigator signature” (example below) must be added* ***if required by the sponsor****, but this may not replace the line for the “person obtaining consent” if this is a different person:*

**Investigator Signature**

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

My signature above signifies that the study has been reviewed with the study 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/substitute decision maker (SDM) 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/SDM.

⬜ The person signing below acted as a translator for the participant/SDM 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/SDM. I confirm that the participant/SDM named above was read the information in the consent document and that the participant/SDM 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)

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

Role of person assisting in the consent process at Holland Bloorview