**Observational Informed Consent form: Information and template FOR PARticipants**

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

The Observational 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 applicable 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 outlines some consent form sections where the SickKids specific language **must** be used.

Please note that a 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 study, 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 version of the updated consent form

**Consent to Participate in a Research Study**

**Participant Consent**

**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, 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 {insert department} Contact number 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 Contact Number Contact Number 416.813.####

Jane Dave, Nurse Practitioner, Division of Contact Number Contact Number 416.813.####

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

**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 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 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 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 rather than to their own medical treatment..*

This research study is being done to [insert goals of study]. We hope to find out [insert information].

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. List and describe each test/procedure/survey/interview, how often it is to be done (i.e., every month, every day), the number of times it is to be done, and the amount of time it is expected to take to complete each research activity. Include whether the test/procedure is different from the current standard of care or part of their typical care (i.e., an ‘extra’ sample of blood will be taken, you will be asked to complete a survey).*

Your participation in this study will involve [number of study visits and their duration]. The overall study will take [length of time of entire study].

You will be asked to [describe research activity that the participant will be involved in]

**If the study is a registry:**

This study is a long-term registry. This means that, if you agree to participate, we will collect information about you over the course of <insert time frame>. *Describe which activities will occur over the course of the registry (if questionnaires, collection of samples, review of health charts, see examples below). Describe how much time this will add to regular clinic visits and if any additional visits will occur.*

**If the study involves surveys/questionnaires:**

You will be asked to complete # questionnaires that will take about <insert approx. time to complete>. The questionnaires ask about <insert content of questionnaires>. *NOTE – it should be clearly stated if parents need to complete questionnaires or if the study team will help the participants to complete questionnaires.*

**If the study involves interviews:**

You will be asked to participate in an interview. A study team member will meet with you at location (e.g., SickKids, your home, a place in the community) to ask you questions about <insert content of interviews>. The interview will take about <insert approx. time to complete>.

**If the study involves focus groups:**

This research study involves a focus group. This means the study involves an interview and discussion in a group setting. There will be about # participants in the focus group. You will be asked about your opinions/perceptions <insert> on <insert subject matter>.

**If audio recording:**

The interview/focus group (or other procedure, as applicable) will be audio recorded. The audio recording will be transcribed after the interview/focus group and will be analyzed by the research team. The transcription will be done by <insert who, e.g., members of the study team, a professional transcription service>. Your name or any other identifying information will not be included during the recording, except your voice. The audio recording will be destroyed after it has been transcribed and checked for accuracy <if otherwise state it here and explain>.

**If video recording:**

The interview/focus group (or other procedure, as applicable) will be video recorded*. Explain what parts of the participant will be video recorded. Will it include their face? What will be done to remove the identifiable information from the video, if any? How will the videos be analyzed, for what purpose, and by whom?*

**If the study involves review of health charts/medical records:**

As part of this study we would like to review your health chart. We will collect information about [detail the data that will be collected; e.g. age, symptoms, the medicines you take, the treatment you’ve received, results from clinical tests etc. – be specific where possible].

**If images obtained as part of standard of care will be used in the study:**

We will collect <image type, e.g., MRI images of your knee joint> that were or will be obtained as part of your usual care. If applicable:

**If the study involves imaging:**

*Describe the procedure the participant will have to undergo for the imaging and include the time (number and length of visits) required for the procedure. If applicable, describe use of anesthesia or contrast agent.*

We will take images of <describe what will be imaged, e.g., brain, heart, etc.>. We will use <describe imaging modality, e.g., x-rays, MRI, ultrasound, camera etc.> to take these images.

**If the study involves a complicated schedule of study activities, the REB suggests using a table to clearly outline what research procedures will be occurring at which visit. Example:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Visit 1 | Visit 2 | Visit 3 | Visit 4 | Visit 5 |
| Procedure 1 | X |  | X |  | X |
| Procedure 2 | X | X |  | X | X |
| Procedure 3 |  | X |  | X |  |
| Procedure 4 |  |  | X |  |  |

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

**If the study involves collection and analysis of biological samples:**

*Describe what sample types will be collected, in what amounts, how they will be collected, the intervals at which they will be collected, how they will be analyzed, and the purpose of the collection. For blood samples, describe amounts to be drawn in ml and tea/tablespoons. Describe the timing of the samples, and if they will be matched to clinical tests, if applicable. Describe what will happen to the samples after they have been analyzed (destroyed (when?), stored (how long and where?)).*

The following samples will be collected from you: [Insert samples to be collected]

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 information is also 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…)

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

*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].

**If the study involves genetic research:**

*Insert appropriate language from the* [*Genetic 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/samples/images/recordings will be being sent outside of SickKids:**

We will send information we get about you/your samples/images/recordings to [name of institution(s)]. [If applicable:] We will not send any information that could identify you [please adapt this sentence if you are in fact sending potentially identifying information (e.g., non-de-identified photos) to an external site]. *Describe how information will be sent securely.*

**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 should also be addressed. 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%284%29.docx)

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.

If there are no known harms:

We don’t know of any risks or harms associated with participating in this study.

When there is blood draw for research purposes:

There is a possibility of pain, bruising, swelling or infection related to the blood draw. These discomforts are minimal and brief.

If the interview/survey 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 and/or the interview, you may experience some anxiety, emotional and/or psychological distress due to the nature of the questions. You can skip questions, take a break or stop answering at any time.

If your responses indicate 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 are in need of urgent care as result of participating in this research study, we will intervene according to routine clinical care practices.

Use of images:

If unique features like birth marks or tattoos are captured in the photos taken for this study, there is a potential risk of loss of confidentiality.

Audio Recording:

There is a potential risk of loss of your confidentiality because even though your name will not be part of the audio recording or the transcription, your voice may still be identifiable as your voice. If anyone mentions identifiers (e.g., your name), during the recording, this may identify you.

Focus Group:

Although the researchers will take every precaution to maintain confidentiality of the data, the nature of focus groups prevents the researchers from guaranteeing confidentiality. It is possible that some focus group members may repeat things said in the meeting. The researchers will ask participants to respect the privacy of fellow participants and not repeat what is said in the focus group to others.

Inconvenience of time:

There is an inconvenience of time. Each study visit will take about ## minutes/hours, for a total of ## minutes/hours for the entire research study.

Inconvenience of additional visits to SickKids:

There is an inconvenience of travel as you will have to come to SickKids for ## research visits.

Confidentiality risk (for all studies):

Despite protections being in place, there is a risk of unintentional release of information. Even though the risk of identifying you from the study data is very small, it can never be completely eliminated.

If the study involves genetic research:

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

**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 child’s involvement in this research study is small.

OR

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.**

**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 [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.
* Tell the study doctor if you are thinking about participating in another research study.
* *If fasting is required prior to the study visit:* Make sure you do not eat for [state duration of fasting (i.e. 8, 10 or 12 hours) before (specify which visits require fasting).
* Ask your study team about anything that worries you.
* Tell the study staff if you change your mind about being in this study.

**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 consent to 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 you name and voice in presentations or publications in the format of quotations. You have the option to refuse 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. [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 data that has been included as part of the analysis or that has 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 your 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

**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 or your child, 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 and/or your family will not be paid to be part of this study. If costs reimbursed: However

we will reimburse you and/or your family 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 and/or your family expenses that you or they have incurred up until that point.

If no payment/reimbursement:

We do not anticipate any additional costs to you and/or your family 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 you and/or your family, you will have to provide the following required information about your parent/SDM: their full name, birth date, full address, and contact details (phone number(s) and or email address). Your name and anything that can identify you 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 you. 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 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 study information to be sent to you and/or another person such as your treating doctor, a member of your 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 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 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.*

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

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.

If the study involves genetic research:

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

**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)**

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.

**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* 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.