**BIOBANK Informed Consent form:**

**FOR PARTICIPANTS**

NOTE:

This is a template.

Please adjust to suit research project.

Template Version: October 7, 2020

**PREFACE**

Remove this **Preface** before finalizing and distributing the Biobank Participant Consent Form.

The Biobank Informed Consent Form Template has been designed to meet current regulatory, institutional and ethical standards. This template should be used when a) the main purpose of the research is to develop a biobank; or b) a biobank is an optional component of a broader, complex study that requires a separate biobank consent form.

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.

**NOTE:** 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.

**INSTRUCTIONS ON HOW TO USE THIS TEMPLATE**

The template includes the framework for organizing your Biobank Participant Consent Form, as well as instructions and example text.

*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 grammatical errors.
* After all edits have been made, all text should be black
* 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 Biobank**

**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 (Study Doctor):**

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

**Example:**

Dr. Jane Smith, Division of {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.####

**Biobank Administrator/Manager:** Include the name and telephone number of at least one research contact.

**24 Hour Contact Information:**

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

Pager: (416) 123-4567

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

**Study Sponsor and/or Funder:**

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

***For SickKids-initiated studies****, the Sponsor should be SickKids. If funding is provided by a grant or other funding source, please provide this information as well.* ***For industry-sponsored studies:***  *the Sponsor and funder is usually the same company.*

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

**Conflict of Interest:**

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

If there are no conflicts, state:

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

If a conflict exists, see below example language

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

**OR**

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

**OR**

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

1. **Introduction**

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

We would like to invite you to take part in our biobank. This consent form describes the biobank 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. 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 trusted community. Participation in the study is voluntary, and you are not under any obligation to participate.

1. **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.*

Biobanking involves the collection of your biological samples or tissues to store for future research use. Biological samples include fluids (such as blood) and tissues which are collected from you during a routine or special procedure. A biobank is a type of facility that receives, stores, processes and distributes biological [samples](about:blank#Biomaterials) as well as data related to those samples. Biobanks provide scientists with access to the samples and study data to conduct other research.

The [name] Biobank was created to collect and store biological samples and health information of children with [specify condition] and their families. The biological samples and health information collected will be made available to medical researchers from SickKids and other institutions [specify whether this includes or exclude industry] to better understand what causes disease in children and families. The ultimate goal is to improve the diagnosis, treatment and prevention of diseases in children.

If the study involves genetic research:

*Explain why genetic research is being done as part of this study. Clearly state the type of genetic testing that will be done. Refer and insert appropriate language from the Genetics Research Consent Form Language document.*

1. **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.

1. **What will happen in this research study? What sample(s) will be collected as part of this study**

*Describe what participation entails in this study. Describe the sample types that will be collected, in what amounts, how they will be collected, the intervals at which they will be collected, how often samples 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?)).*

Your participation in this study will be for one year. Participation involves 3 study visits (study entry, 6 and 12 months). Each study visit will take between 30-60 minutes to complete the online questionnaire and blood collection.

If you are collecting **Blood (Collecting Samples with Routine Procedures**):

[specify amount e.g., about XX mL (or YY teaspoons] of blood will be taken with a needle from a vein in your arm. Blood samples will be taken [specify timing – e.g., once before you take the study drug, 1 and 4 weeks after you start the study drug and 4 weeks after you stop the study drug.]. If possible, these samples will be taken at the same time as your study-related or clinical tests (e.g. at entry to the trial).

We will collect up to [specify amount of sample that will be collected]. Your samples will be maintained in [name] Biobank at [location]. The samples will be kept [specify amount of time, or… until they are used up, destroyed or returned to the hospital where you had your surgery or biopsy].

If you are collecting **Bone Marrow:**

As part of your clinical care, you may need to undergo a procedure called a bone marrow aspiration or a bone marrow biopsy. If you agree to provide the Biobank with your samples, we will ask your doctor to take an extra amount (specify minimum amount) for the biobank. The extra amount of bone marrow or bone will only be taken if your doctor says it is safe to take this extra amount.

If you are collecting **Cheek Swabs:**

A cheek swab collects cells that line your mouth. This is a painless procedure where a cotton swab is rubbed on the inside of your cheek.

If you are collecting **Saliva Samples:**

[specify amount e.g., about XX mL (or YY teaspoons] of saliva will be collected from you. To collect the saliva, you will need to spit into a tube.

If you are collecting **Stool or Urine Samples:**

You will be provided with a special container to provide a stool/urine sample. If possible, leftover samples from routine care will be collected.

If you are collecting **Tissue:**

Undergoing surgery or procedure which requires extra tissue removal

When you undergo your surgery (specify the original planned procedure) or clinical procedure (specify, ex: fine needle aspiration biopsy), the surgeon/doctor doing the procedure will remove (a small extra amount of tissue, extra tissue which will need to be specified). This will be aside from the tissue required by your treating doctor. Extra tissue will be removed only if your treating doctor says it is safe. If the treating doctor determines that it will not be safe to take the tissue required for biobanking, the extra tissue will not be taken.

Collecting left-over tissue or specimens following testing:

When you undergo your surgery or clinical procedure, any tissues or body fluids removed are usually sent to the Pathology laboratory for testing. The testing is done to help diagnose your condition. The amount of tissue taken is usually more than enough to do one test. This ensures that if re-testing is needed, there is enough tissue available to verify test results or do additional testing. In some cases, there will be tissue or fluids left-over after all the testing has been completed. This tissue or fluid may either be saved or discarded.

We are asking you to consent to donate any left-over tissue or fluids after testing has been completed. If you consent to be part of the Biobank, we will take any left-over tissue or specimens with your doctor’s consent. Even if you have signed this consent form, we will not take any left-over tissues or fluids if your doctor says that this may be needed for additional testing or storage for future testing.

If you are collecting **Other Body Fluids:**

All organs of the body are lined with a fluid substance. Your brain and spinal cord are surrounded by cerebrospinal fluid (CSF). If your treating doctor does a spinal tap to get CSF for testing, (state minimum amount for storage) may be taken for the Biobank but only if your doctor says this is safe.

Your lungs and digestive organs are also surrounded by fluid. These organs may also contain fluids (describe here).

**Old Samples:**

You can donate any of your old samples that were initially collected for medical purposes such as diagnosis, monitoring of treatment or progression of disease. These are called archived samples and are stored at the SickKids Department of Pathology and Laboratory Medicine (DPLM). To donate any of your archived samples, your treating doctor will let you know if the samples are no longer needed or that there are enough samples left over for possible future testing you may need.

All the samples collected from you for this study will be de-identified by replacing your identifiable information such as your name with a “study number”.

**Health Chart Review:**

*Specify all information being collected: medical / health history related to the condition being studies, family history, results of tests and procedures including blood work, imaging, genetic testing, results of neuropsychological assessments, notes from referrals, admissions, clinic visits, copies of images, follow-up on vital status, etc.*

As part of this study, we would like to review your medical / health chart. We will collect this 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, imaging, photographs etc. – be specific where possible].

All personal health information that is collected about you will be de-identified by replacing your identifiable information such as your name with a “study number”.

1. **What type of research will be done on my sample(s)?**

*Describe the anticipated research / uses of the samples and study data and provide as much detail as possible.*

Your samples and associated information may be used for [select an option below]

Tests that will be done on all samples, list what the tests are and the purpose for doing them.

If no tests will be done after collecting samples, state that samples will be collected, de-identified and stored for future research purposes.

Future research related to your medical condition will be done.

Future research that will be done on your samples include research that is related to your medical condition but also research that is not related to your medical condition. Future research also means testing that are not known at this time, including genetic testing.

If there will be biomarker research:

The research done on your samples may include looking at certain proteins called “biomarkers” that are believed to be important in the [specify: incidence of disease, response to treatment, growth of cancer in tumours, etc.]. This biomarker research may help researchers understand:

* How your disease may behave with or without treatment,
* What kind of side effects a person will have when they receive different kinds of treatment,
* How the disease might respond to the study treatment,
* Who will benefit the most from this type of treatment.

If there will be future unknown testing:

It is not possible to predict all of the ways in which samples stored in biobanks might be used in the future, so it is not possible to tell you exactly how your sample will be used. However, this future research may include (provide examples, e.g., genetic research).

If the study involves genetic research:

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

1. **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 (if hospitalized, family physician, etc.) and questionnaires (address, provincial medical number) collected from/about you during the study. This information is necessary to understand [include the reason].

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

Some of the information collected for this biobank includes identifiable information about you, including: [list all potentially identifiable information that will be collected for linking purposes. Please be sure to list all direct identifiable information that will be collected (i.e. name, MR,). If indirect identifiable information (i.e. telephone number, address, postal code) will be collected for purposes of contacting the participants, please state what will be collected and for what purposes.

Indirect identifiable information such as full date of birth, solid organ transplant date, OHIP/ health care number, etc.) are collected as part of research data. 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].

Identifiable information collected for linking purposes will not leave SickKids. Your personal health information will be maintained securely and only shared with those on the study team as necessary. Information used to link to provincial data will also follow security requirements by each province and any linking information will be destroyed following standard procedure.

**6.Mandatory parts of this Biobank:**

Sample and data sharing are fundamental to this study. This means it is required for the research study. All de-identified biological samples, including genetic samples, and health information will be used only by academic researchers who have appropriate approvals to conduct research approved by the Principal Investigator and will not be sold.

Your de-identified samples, including genetic samples, and de-identified health information, including your genetic sequencing data will only be shared with other researchers once they have gone through a scientific review process with study investigators and also ethics review committee at their respective institution. Any data or samples that are sent to other researchers will contain only a unique identifying number; and date of collection and they will NOT contain any personal identifiers such as name or address. Researchers from other universities, the government, and drug- or health-related companies can apply to use the samples. The coded data in the controlled access biobank meets international security and safety standards.

External researchers who would like to do future research using your samples will sign agreements with the Hospital for Sick Children. These agreements will control how your samples and study data will be used. They will not be permitted to disclose or to transfer study data or samples to anyone else if not stated in the agreement. They will also not be permitted to use samples or study data for purposes other than those included in the agreements. Researchers will also agree that they will not attempt to re-identify you from their study data and samples. Other researchers will not be permitted to disclose or transfer samples or data except to as required by law or pursuant to agreements that impose similar confidentiality obligations as SickKids imposed on the researcher.

The information from the biobank will be available only to researchers who have received Research Ethics Board approval for their research.

By participating, you agree that your de-identified samples and de-identified data, including genetic samples and data, may be used for future research. This is a mandatory part of the study. If you don’t want your de-identified data, samples or genetic information to be shared with academic researchers, you cannot be part of this study.

**Sharing of your samples and data is a mandatory part of this research study:**

Genetic sequencing data (e.g. whole exome sequencing, whole genome sequencing), and phenotype data (e.g. [insert examples]) will be shared with researchers as approved by the REB. This is a mandatory part of the study, which means it is required for the research study. If you do not consent to the mandatory parts of the study, you cannot be part of this study.  This information will be shared two ways:

1. Controlled-access Database for Coded Genomic and Research Data

Your “de-identified” genetic and phenotype data will be available to anyone who requests and is approved to access the data bank. Because genetic and phenotype data may contain potentially rare or sensitive information, which when taken together increases the chance of identification, we will review the applicant and put agreements (signed contact) in place. The [insert how this will be reviewed prior to the release of this information] will review all applications for access to verify that the proposed study has received ethics approval from the relevant committee (when required) and that the study fits within the objectives of the REB approved international database. Applicants may include researchers at universities, hospitals, government agencies and some for-profit companies around the world who may be conducting research projects not only related to [insert condition(s)], but also on other medical conditions. The coded data in the controlled-access database meets international security and safety standards and may be stored in different countries.

1. Open-access Database for Anonymized Genomic Information

Your genetic data (e.g. whole genome sequencing) will be “anonymized” meaning that all personal identifiers (e.g. name, address), as well as any research codes will be removed and it will no longer be possible to link your genomic information with other information (e.g. medical information). However, it will be possible to tell which genomic information comes from the same family, without identifying the family. This anonymized genetic data will be publicly available to anyone without restriction. This is known as open access. Although only experts will know how to interpret this information, there is a chance that somebody could connect you with the information from the study of the sample you give. Researchers who access the open-access database may be conducting research projects not only related to [insert condition(s)], but other types of research, including research on other medical conditions.

1. **Optional components of this Biobank:**

*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 is 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).*

**Sharing your samples and information with for-profit companies:**

Sharing your de-identified biological samples and health information with for-profit commercial companies such as pharmaceutical companies are optional. You will be asked to provide your consent below.

A for-profit company may be a pharmaceutical company that wants to make a new drug or test a currently approved drug for another disease or population. It may also be a biotechnology company that develops new ways to treat or diagnose disease.

If you consent for for-profit company sharing, SickKids may receive money in exchange for your samples and study information. Any funds we receive will support our new and ongoing research on.... Your samples and health information will be identified only by a unique ID number assigned to you.

|  |  |
| --- | --- |
| Initial | Options: |
| \_\_\_\_\_\_\_\_ | **Yes**, I agree for my research information collected in this study to be used for research purposes with for-profit company such as device manufacturers and pharmaceutical companies. |
| \_\_\_\_\_\_\_\_ | **No**, I do not agree for my research information collected in this study to be used for research purposes with for-profit company such as device manufacturers and pharmaceutical companies. |

We would like your permission to use your de-identified and or anonymized genomic sequencing data in future research with for-profit companies like pharmaceutical companies. Please initial next to your preference:

|  |  |
| --- | --- |
| **Future Research of Genomic Sequencings data about me:** | |
| Initials | **Yes**, you can use my de-identified and or anonymized whole genome sequencing data for future research purposes with for-profit companies. |
| Initials | **No**, you cannot use my de-identified and or anonymized whole genome sequencing data for future research purposes with for-profit companies. |

**If organoids will be created, include the following:**

We may use the cells taken from your [specify source of cells, e.g. skin] to create what is called an “organoid”.  An organoid is a group of cells, grown in the lab, that are designed to mimic organ structure, such as liver or kidney, and its function.  Organoids can be used to help understand diseases and treatments for them.

Below are options for participation. Please initial next to your preference(s).

|  |  |
| --- | --- |
| **Future Research of Cell Lines:** | |
| Initials | **Yes**, you can store my cell lines for future research purposes. |
| Initials | **No**, you cannot store my cell lines for future research purposes. |

|  |  |
| --- | --- |
| **Future Research of Cell Lines with for-profit companies:** | |
| Initials | **Yes**, you can share my cell lines with for-profit commercial companies such as pharmaceutical companies. |
| Initials | **No**, you cannot share my cell lines for-profit commercial companies such as pharmaceutical companies. |

**Genomic Sequencing Data:**

Genomic sequencing allows us to test a person’s DNA and find variations in DNA sequence for thousands of their genes at the same time. Your genomic sequencing data is unique to you and will have important health information about you.

We would like your permission to use your de-identified and or anonymized genomic sequencing data in future research. Please initial next to your preference:

|  |  |
| --- | --- |
| **Future Research of Genomic Sequencings data about me:** | |
| Initials | **Yes**, you can use my de-identified and or anonymized whole genome sequencing data for future research purposes. |
| Initials | **No**, you cannot use my de-identified and or anonymized whole genome sequencing data for future research purposes. |

**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. |

1. **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.
* Ask your study team about anything that worries you.
* Tell the study staff if you change your mind about being in this study.

1. **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. Describe generalizable/societal benefits.*

There are no direct benefit(s) to you for participating in this biobanking study.

Because this research is on-going and will take many years, you will likely not directly benefit from being in this study. However, this research may lead to better diagnosis and treatment in the future for patients who have the same or a similar condition as you.

1. **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.*](about:blank)

When you give your blood sample for genetic testing or research through a databank or for future research, you are sharing genetic information, not only about yourself, but also about biological (blood) relatives who share your genes or DNA. Genetic information can never be fully de-identified. Genetic information is unique to every person, just like a fingerprint. This means that theoretically you can be identified by your genetic code.

Procedures have been put into place that are designed to make it very difficult for the results from genetic research to be linked to you.  While this is very unlikely at this time, due to the rapid pace of technological advances in genetics, there may be a risk that the genetic information in the samples could be linked back to you. There is also a risk of unintentional release of information. The potential re-identification or unintentional release of your information could lead to loss of privacy and to possible future discrimination against you or your biological relatives. The potential future use of genetic information is unknown and therefore not all potential future risks are known. You should be aware that genetic information cannot be protected from disclosure by court order.

There is a possibility of pain, bruising, swelling or infection related to the blood draw. These discomforts are minimal and brief. When completing the questionnaires, you may experience some anxiety, emotional and / or psychological distress due to the nature of the questions. You can skip any question(s) that make you uncomfortable, take a break and / or stop answering the questions at any time. Each study visit will take about [insert time] for the blood collection and completion of the online questionnaire. Although questionnaires will be completed on-line or by phone, there is an inconvenience of travel, for the blood collection.

Despite protections being in place, there is a potential 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.

For biospecimens collected as part of routine or diagnostic procedures:

There are no additional physical risks to you because samples will be collected at the same time as any procedure your treating doctor has planned.

For blood collected during special procedures:

For blood and blood product collection that is not done at the same time as routine blood testing for medical care, there is a risk of infection, bleeding, or bruising when a blood sample is collected from your vein. This risk is not greater than the risk of a regular blood draw.

For Biopsies:

The risks of a biopsy include bruising, pain, bleeding, and rarely an infection at the biopsy site infection or blood clot underneath the skin.

If the study involves genetic research:

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

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

***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.*

Yes, 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. The care you receive at SickKids will not be affected by your decision to participate or not participate in this 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 decide to leave the study, you can contact a member of the study team to let them know.

1. **Can I withdraw my samples and data from the research study?**

If you no longer want your samples to be used in this research study, you can request to have your samples withdrawn and destroyed. If you decide to withdraw from the study, your samples will no longer be shared, and no new samples will be collected, and samples stored in the Biobank will be destroyed as of the time of your notification. However, it may be impossible to withdraw those already shared or when combined or analyses or already published.

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

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.

If you would like to withdraw your de-identified data from the biobank, please let a member of the study team know. It the data is already shared or used of analysis or already published, it will not be possible to withdraw your data, but no new data will be collected.

1. **Who will have access to my sample(s) and study data?**

*Describe who will have access, how access will be obtained and under what conditions access will be granted and whether samples will be sold. Describe any potential for linking with any other databases or registries and the possibility transfer of samples and/or information outside the country. Ensure that you specify who these samples/data will be shared with, for example, only other SickKids investigators, external academic researchers, for profit industry, etc.*

Examples:

Your samples and study data will be used only by scientists approved by the biobank governance committee and will not be sold.

External researchers who would like to do future research using your samples will sign agreements with the Hospital for Sick Children. These agreements will control how your samples and study data will be used. They will not be permitted to disclose or to transfer study data or samples to anyone else. They will also not be permitted to use samples or study data for purposes other than those included in the agreements. Researchers will also agree that they will not attempt to re-identify you from their study data and samples.

The samples and data will be available only to researchers who have received Research Ethics Board approval for their research.

1. **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 child’s personal health information / personal information to them. The link between the study number and your identity will be safeguarded by the SickKids study staff and will not be available to the (Sponsor/Funding agency/Coordinating centre). SickKids guidelines include the following:

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

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

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

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

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

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

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

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

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

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

If potentially identifiable data will be sent outside of SickKids:

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

Include what potentially identifiable information will be collected:

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

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

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

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

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

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

If 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.

*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 their 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.

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.

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*](about:blank)

1. **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.*

**Incidental findings (if applicable):**

[*See Genetics Research Consent Form Language – language from this document must be inserted here*](about:blank)*.*

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 did not 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.

1. **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].

1. **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 biobank 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 family, such as:

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

* Example 1

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

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

You will not be paid to be part of this study. If costs reimbursed: However we will reimburse you 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 for expenses you have incurred up until that point.

If no payment/reimbursement:

We do not anticipate any additional costs to you for participating in this research study because <insert why they will not incur additional costs>

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.

1. **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.

1. **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.

1. **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.

1. **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].

1. **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.

1. **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].

1. **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 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 Biobank 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) |

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 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.