**Secondary USe Informed Consent form: Information and template FOR PArticipants**

**Version Date: February 3, 2020**

**Instructions:**

The Secondary Use Study 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

**How to use this template:**

*GREY Highlighted text*: General instructions for the section

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

**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
* Use a size and font of text that is consistent and easy to read (size 11 or larger is recommended)
* Define all acronyms and abbreviations when they first appear
* Use the term ‘study doctor’ when referring to physicians involved in the clinical trial, to ensure there is no confusion with the treating or primary care doctors
* Ensure that the final form is properly formatted and free of spelling or grammar errors.
* After all edits have been made, all text should be black
* If there is a possibility that participants will have capacity to consent, both a parent/surrogate decision maker and participant version of the consent form should be submitted.
* If the REB requests changes to the consent form, submit both clean and tracked changes version of the updated consent form

**Consent to Participate in a Secondary Use 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 (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.####

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

**24 Hour Contact Information:**

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

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 participant is being asked to participate and describe the background information relevant to the study.*

You are being invited to participate in a study that involves [provide a brief description of study activities – e.g., a review of your medical records and/or analysis of a biological sample you previously provided.] Your are being invited to participate in this study because you have [explain the main features of the population to which the research applies]*.*

**Why is this study being done?**

*Explain the purpose and specific goals of the 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.*

The research is being done to [insert purpose/significance of conducting the study].

**Example 1:** Almost half of the children with juvenile idiopathic arthritis will develop arthritis in the knees or ankles. It is very rare for the condition to affect other joints in these patients. We are doing this study to see how juvenile idiopathic arthritis evolves in children who have arthritis in an unusual joint. We want to learn more about these patients to see if they require special care.

**Example 2:** The research is being done to document the outcomes of artery-only ear replantation in children. Ear replantation is very challenging, even for the most experienced surgeons. Artery-only ear replantation is an option to treat complicated cases of ear amputation, but little is published on the results of this surgery.

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 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 if I join this study?**

*Describe the design of the study. See suggestions below. If these suggestions are not applicable, provide a lay description appropriate to your protocol. Specify all information being collected: medical 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.*

To participate in this study, you do not need to do anything other than consent; there will be no additional medical visits or tests. This study involves looking at your medical records and/or analyzing a [type of biological sample] that was already collected from you during [medical procedure or participation in another study].

*If the study involves the* ***secondary use of data****, describe the data source (e.g. charts), and the type of information you will collect:*

We will collect information that was entered into your medical record between [time period of chart entries]. [If a different secondary data source will be used, provide information about this here]. We will collect information (and images, etc.) about [detail the data that will be collected; e.g. age, symptoms, the medicines you take, the treatment you have received, results from clinical tests etc. – be specific where possible].

*If the study involves the* ***secondary use of already collected samples****, describe what samples will be used, what tests will be performed, what information you hope to get from these tests, any possible incidental findings, and what will happen to the sample once the study is complete:*

We will use [specify the type of samples, e.g. blood samples] that were already collected from you as part of clinical care OR as part of your participation in the study titled XX. We will [provide lay explanation of the tests that will be performed on the sample and the purpose of this test, e.g., test the blood to learn about the different proteins in it].

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

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

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

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

If data/samples will be being sent outside of SickKids:

We will send information we get about you (and/or your sample) 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].

If data/samples will be shared with Industry Partners:

An industry partner is an organization that 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 industry partner 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 industry partners 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 industry partners such as device manufacturers and pharmaceutical companies. |

**What are the risks of the study?**

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.

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

You will not benefit directly from participating in this study. We hope that the information learned from this study can be used in the future to help other people with a similar disease and/or health condition.

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

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

If incidental findings are possible, include the following:

During the study, the researchers may learn something about you that they didn’t expect. For example, the researchers may [insert anticipated incidental findings and describe anticipated management plan – what types of information will be disclosed, if any and under what circumstance, e.g.if any new clinically important information about your health is obtained as a result of your participation in this study, you will be given the opportunity to decide whether you wish to be informed of that information.]

If the study involves genetic research:

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

**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.*

You can change your mind at any time during the research study. You do not need to give a reason to withdraw from the study. 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 the Principal Investigator or a member of the study team to let them know. They will ensure the samples are (describe what will happen to samples if participant withdraws consent), e.g., returned to the hospital from which they were obtained or destroyed.

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

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

If samples will be made anonymous at a certain point

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

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

There are no costs associated with participating in this study.

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

You will not be paid or reimbursed for your participation.

**What personal health information will be collected about me 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 information from your medical records. The study team will only collect the information they need for this study.

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

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

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

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

**How will my privacy be protected?**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

If potentially identifiable data will be sent outside of SickKids:

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

Include what potentially identifiable information will be collected:

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

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

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

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

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

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

If 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.*

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*](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 your child. You can search this website at any time.

**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 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.