**Case STudy/Series Informed Consent form: Information and template**

**Version Date: May 22 2018**

The Case Study/Series 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 and that the order of items (headings) is maintained. Alterations to the structure of the headings must be justifiable. 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) have been included. Note that the checklist outlines some consent form sections where the SickKids specific language **must** be used.

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

**How to use this template:**

*GREY Highlighted text*: General instructions for the section

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

**BLACK text:** 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 Case Report/Series**

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

*Both case reports and case series require consent. Case series involving 3 or more patients, or contribution of a single case to a case series requires REB review. Change language to* case report *(for 1-2 participants) or* case series *(for 3+ participants).*

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

**Principal Investigator:**

Include the name, department and contact information (i.e., telephone number) of the SickKids Principal Investigator.

**Co-Investigator(s):**

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

**Study Coordinator(s)/Research Contact:**

Include the name and telephone number of at least one research contact.

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

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

**Conflicts 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. See the Consent for Clinical Trials consent form template for specific examples.*

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

If the study team has no conflicts of interest:

The study team has no conflicts of interest to declare related to this study.

**Introduction**

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

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

We would like to invite you to take part in our research study. This consent form describes the research study and what it means to participate. Before deciding to take part, please take as much time as you need to ask any questions and discuss this study with anyone at SickKids, or with family, friends, or your personal physician or other health professional. Participation in any research study is voluntary (you do not have to participate if you don’t want to).

**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 invited to participate in a case series/case report because you have [explain the main features of the population to which the research applies]

For case series:

A case series is typically used to share new information about patients with a common medical condition that may be useful for other physicians and researchers.

For case reports:

A case report is a detailed description of the symptoms, signs, diagnosis, treatment, and follow-up of an individual patient. They usually describe an unusual case.

It involves reviewing health information that already exists in the medical record

**Why is this study being done?**

*Explain the purpose of the study in lay terminology. Examples are provided below.*

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

**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 and report a successful case of artery-only ear replantation in a child. 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. We want to publish your case to show other doctors that this surgery can give excellent results when good care is given after the surgery.

**What will happen if I join this study?**

To participate in this study, you do not need to do anything other than consent; there will be no additional medical visits or tests. The study team will collect information (and images, etc.) from your medical chart [report any other data sources].

The information about you that we wish to use for this study are the following [provide details on information that will be collected as part of case series – be specific where possible:

* Demographic information (e.g., gender, ethnicity)
* Full or partial date of birth
* Types, dates and results of medical tests or procedures
* Medicines and treatments provided

For case series:

This case series will involve [number of participants both at SickKids and total across all sites; e.g., two patients at SickKids and twenty patients internationally]. If multi-centre: We will share information we collect in this study with [institutions where data will be sent].

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

There is a small chance of a break in confidentiality but we will follow all SickKids policies and procedures to try to make sure this does not happen.

**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.

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

You can change your mind about participation 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 the participant can withdraw information collected prior to withdrawal (otherwise, describe the limits of withdrawal):

If you decide to leave the study, you can ask that the information that was collected about you not be used for the study, unless the study results are already published.

To leave the study, you can contact the Principal Investigator or a member of the study team to let them know. ***Note:*** *requiring a written notification is not acceptable. It is the study team’s responsibility to document the request. Verbal notification is sufficient. Parents/patients should not be asked to go through the additional burden of writing a letter for documentation purposes.*

**How will my privacy be protected?**

*Language in this section is mandatory, unless otherwise indicated. Note that specific information that will be collected about participants through a chart review, surveys, questionnaires etc. should be described in the study procedures section.*

We will respect 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. [The Sponsor/Funding agency/Coordinating centre] is also committed to respecting your privacy.

If you decide to participate in this study, the SickKids research team (study investigators, coordinators, nurses, and delegates) will collect personal health information about you, including things learned from the study procedures. They will collect only the information they need for this study. “Personal health information” is health information about you that could identify you.

Indicate how identifiable information will be protected:

All information collected about you will be “de-identified” by replacing your identifiable information (i.e., name) with a “study number”. Only the “study code key” can connect the information collected about you to your identity. The study code key will be safeguarded by the SickKids research team and will not be available to the (Sponsor/Funding agency/Coordinating centre). Even though the risk of identifying you from the study data is very small, it can never be completely eliminated.

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 or samples will be sent outside of Canada:

Any study data 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. All information will be transferred in compliance with all relevant Canadian privacy laws.

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

* Representatives of the SickKids Research Ethics Board and/or Research Quality and Risk Management team
* Sponsor Name, the company that makes the DRUG/DEVICE (including trade name) / INTERVENTION}, and its representatives and partner companies;

The research team will keep any personal health information about you in a secure and confidential location for (# of years) years and then destroy it according to SickKids policy. *SickKids policy recommended standard is 7 years for non-regulated studies. However, sponsor, publishing journal or professional affiliation standards for record retention should apply when necessary.*

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.

If the patients clinic chart will be noted of their participation

*Note: The REB recommends noting participation in charts only when participation may affect care, or if participants are likely to be approached for multiple research studies If participants are not SickKids patients, this section is not applicable..*

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

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

If you have any questions about this research study, you can contact the (Principal Investigator/study coordinator), [NAME] at [phone number].

**Research Ethics Board Contact information**

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/my child’s medical records and specimens as explained in this consent form,
4. I do not give up any of my or my child’s legal rights by signing this consent form,
5. I understand that my/my child’s family doctor/health care provider will/may be informed of my participation in this study
6. I have been told I will be given a signed and dated copy of this consent form.
7. I agree/agree to allow the person for whom I am responsible to take part in this study.

For participant consent:

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

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

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

For parent/guardian consent:

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

|  |  |  |
| --- | --- | --- |
| Printed Name of Parent/Guardian |  | Parent/guardian signature & date (DD/MMM/YYYY) |

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

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

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

**Investigator Signature**

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

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

**If the participant/surrogate decision maker 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.

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

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

Role of person assisting in the consent process at SickKids