



THE HOSPITAL FOR
SICK CHILDREN

Research Ethics Board

**Research Ethics Board
Research Consent Form Template
For
Retrospective Research Projects**

Title of Research Project:

- The study must be the same as the one provided in the REB application form.

Investigator(s):

- Include the name and telephone number of all investigators including the principal and co-investigators. The principal investigator must be a permanent member of SickKids staff. If an investigator is a student, include explicit acknowledgment of the student's status, the name of the supervisor, and his/her affiliation with the hospital.

Purpose of the Research:

This section should answer the question: "Why do the study?"
It should include a statement that this study involves research.

Description of the Research:

This section should answer the questions: "How will the study be conducted and how will the subjects be involved?"

- For retrospective research projects, the subject's personal health information will be accessed, used and disclosed and this needs to be made explicit in the consent form. Subjects should also be informed that study data will be aggregated for publication and that individuals will not be identifiable.
- N.B. If the study involves using pre-existing photographs, videotaping or sound recordings, there must be completion of a separate consent form for their use.

Potential Harms:

- If there are no known harms to the subjects, this should be stated in one of the following ways:
"There are no known harms associated with participation in this study."

Potential Benefits:

To individual subjects:

- If the subjects will not benefit directly from participation in this study, the following statement should be included: *"You (your child) will not benefit directly from participating in this study."*

To society:

- If society in general or patients with a similar condition may benefit from the results of this study, this should be explained. This statement should be in a separate paragraph from any statement about potential benefits to the subjects.

Confidentiality:

- The following statement regarding confidentiality should be included:

“We will respect your privacy. No information about who you are will be given to anyone or be published without your permission, unless the law makes us do this.

“SickKids Clinical Research Office Monitor, employees of the company funding the study [name] if any, or the regulator of the study may see your health record to check on the study”.

“By signing this consent form, you agree to let these people look at your records. We will put a copy of this research consent form in your/your child’s health record”.

“The data produced from this study will be stored in a secure, locked location. Only members of the research team (and maybe those individuals described above) will have access to the data. Following completion of the research study the data will be kept as long as required by the SickKids “Records Retention and Destruction” policy. The data will then be destroyed according to this same policy.”

Participation:

- The following statements must be included:

“It is your choice to take part in this study. You can stop at any time. The care you get at SickKids will not be affected in any way by whether you take part in this study.”

Or

“If you choose to let your child take part in this study you can take your child out of the study at any time. The care your child gets at SickKids will not be affected in any way by whether your child takes part in this study.”

- The following statement must be added:

“We will give you a copy of this consent form for your records”.

- Parents of subjects should be made aware that assent may be required from their child.

Consent :

The following must be the last section on the form and must be reprinted verbatim for participants who can consent for themselves.

“By signing this form, I agree that:

Consent/Assent Form Version Date

Page ___ of ___

- 1) *You have explained this study to me. You have answered all my questions.*
- 2) *You have explained the possible harms and benefits (if any) of this study.*
- 3) *I know what I could do instead of taking part in this study. I understand that I have the right not to take part in the study and the right to stop at any time. My decision about taking part in the study will not affect my health care at SickKids.*
- 4) *I am free now, and in the future, to ask questions about the study.*
- 5) *I have been told that my medical records will be kept private. You will give no one information about me, unless the law requires you to.*
- 6) *I understand that no information about who I am will be given to anyone or be published without first asking my permission.*

7) *I have read and understood pages 1 to _____ of this consent form. I agree, or consent, to take part in this study.*

Printed Name of Subject & Age

Subject's signature & date

Printed Name of person who explained consent

Signature & date

Printed Witness' name (if the subject/legal guardian does not read English)

Witness' signature & date

If you have any questions about this study, please call _____ at _____

If you have questions about your rights as a subject in a study or injuries during a study, please call the Research Ethics Manager at (416) 813-5718."

OR

For parent/legal guardians or substitute decision makers consenting for their children, a separate consent form must be included with the following final section.

Consent:

"By signing this form, I agree that:

- 1) *You have explained this study to me. You have answered all my questions.*
- 2) *You have explained the possible harms and benefits (if any) of this study.*
- 3) *I know what I could do instead of having my child take part in this study. I understand that I have the right to refuse to let my child take part in the study. I also have the right to take my*

child out of the study at any time. My decision about my child taking part in the study will not affect my child's health care at SickKids.

4) I am free now, and in the future, to ask questions about the study.

5) I have been told that my child's medical records will be kept private. You will give no one information about my child, unless the law requires you to.

6) I understand that no information about my child will be given to anyone or be published without first asking my permission.

7) I have read and understood pages 1 to _____ of this consent form. I agree, or consent, that my child _____ may take part in this study.

Printed Name of Parent/Legal Guardian

Parent/Legal Guardian's signature & date

Printed Name of person who explained consent

Signature & date

Printed Witness' name (if the parent/legal guardian does not read English)

Witness' signature & date

If you have any questions about this study, please call _____ at _____

If you have questions about your rights as a subject in a study or injuries during a study, please call the Research Ethics Manager at (416) 813-5718."



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ASSENT FORM*

- Title of Study
- Investigator(s)
- Why are we doing this study?
- What will happen during the study?
- Are there good things and bad things about the study?
- Who will know about what I did in the study?
- Can I decide if I want to be in the study?

The following statement is suggested “*Nobody will be angry or upset if you do not want to be in the study*” “*We are talking to your parent/legal guardians about the study and you should talk to them about it too*”.

Assent:

The following section must be included at the end of the assent form instead of the consent paragraph:

"I was present when _____ read this form and said that he or she agreed, or assented, to take part in this study".

Printed Name of person who obtained assent

Signature & Date