

Research Consent Form Template (for clinical trial)

Title of Research Project:

- The study title 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 or qualified investigator (for drug trials) and co- or sub-investigators. The principal investigator must be a permanent member of Sick Kids 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.
- To ensure appropriate interpretation of results, research studies that include testing (e.g. psychological testing, dietary assessment, etc.) where the results of the tests or investigations will be reported back to the subject or the subject's parent/legal guardians, a responsible individual (registered psychologist, dietician, etc.) as an investigator or consultant to the project must be identified.
- The name and telephone number of the clinical research project coordinator or clinical research nurse coordinator may also be included.

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?"
- Include a step-by-step description of the research as it will be experienced by research subjects. Be sure to distinguish clearly between those interventions that are part of standard therapy and those that are research.
- For drug, natural health products or device trials, include the approximate number of subjects that will be enrolled at Sick Kids and in total if the study is multicentre.
- All additional hospital visits or prolonged hospital stays for this research must be explained.
- Indicate frequency and duration of specific testing, as well as the duration of the entire study; for studies involving multiple interventions, a table or flow diagram must be included.
- State whether any therapy that the subject was receiving prior to enrollment in the study will (or may) be altered or discontinued as a result of participation in the study.
- If randomization or sequential assignment is to be carried out, explain these terms and the probability of being assigned to each option eg., randomization could be described as 'like the toss of a coin'.
- If blood will be taken, indicate the total volume in teaspoons and ml equivalents. (Please refer to the REB guidelines on the REB website).
- If radiation is involved, indicate radiation exposure in lay terms.
- Review of the patient's health record for the research project must also be mentioned.

- For studies that include pregnancy as an exclusion criteria, the following paragraph should be included verbatim;

“If you are female and able to get pregnant, a urine pregnancy test will be done. If the test is positive, you will not be able to enter the study. The results of the pregnancy test are confidential and will be told to you by one of the study nurses or doctors in private. Every effort will be made to keep positive pregnancy test results private.”

- If future use of the research data beyond the current study is anticipated, this should be explained (e.g. subsequent use of information about your condition, videos, banking of tissue, body fluids or DNA). If the research data/samples are to be destroyed after the study is complete, this should be explained.
- If the study involves taking photographs, videotaping or sound recordings, mention the need to complete a separate consent form. (Specific REB consent form templates are found on the REB website).
- If the study involves DNA testing, mention the need to complete a separate consent form. (Specific REB consent form templates are found on the REB website).

Potential Harms:

- If there are no known harms to the subjects, the following statement should be included verbatim;
“We know of no harm that taking part in this study could cause you.”

- With drug trials or surgical interventions, the addition of the following statement should be considered;

“But there may be harms that we do not know about.”

- If there are known harms to the subjects state clearly:

a) current knowledge regarding the probability of the occurrence of the harm(s);

b) clinical importance of the harm(s); and

c) any relevant knowledge regarding the probability of reversibility; e.g.

“There may be a small amount of bleeding when blood is taken from a vein and there may be slight discomfort and bruising or redness that will usually disappear in a few days.”

- For studies involving potentially sexually active subjects, a statement concerning potential harm to embryo, fetus and nursing infants must be included.

- Information on adverse events must be reported immediately to the REB (see REB guidelines posted to the REB website) and may require revisions to the consent and assent forms.

Potential Discomforts or Inconvenience:

- Discomforts or inconveniences associated with participation must also be stated eg., inconvenience in travelling to the hospital and the time commitment required to participate in the research project.

Potential Benefits:

To individual subjects:

- If the subjects will not benefit directly from participation in this study, the following statement should be included verbatim:

“You (your child) will not benefit directly from participating in this study.”

- If the subjects may benefit directly from participating in this study, this should be stated and the potential benefits should be described.
- For studies that include diagnostic testing, a statement regarding the possibility of unexpected or ‘incidental’ findings should be included.
- A statement regarding the availability of the results of the research for subjects must be added.

To society:

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

Alternatives to participation:

- The likely consequences of not participating in the research should be clearly explained.
- If there is no treatment alternative (i.e. no available therapy), the alternative to participation in the study is no treatment and this should be explained.
- If there is a treatment alternative(s) eg., standard care, the alternative(s) should be identified and described.
- If the research is not about a treatment alternative this section may be deleted.

Confidentiality:

- The following section regarding confidentiality should be included:

“We will respect your privacy. No information about who you are (your child is) will be given to anyone or be published without your permission, unless the law requires us to do this. For example, the law requires us to give information about you (your child) if a child has been abused, if you (your child) has an illness that could spread to others, if you or someone else talks about suicide (killing themselves), or if the court orders us to give them the study papers”.

“Sick Kids Clinical Research Monitors, employees of the funder or sponsor of the study [name], or the regulator of the study may see your (your child’s) health record to check on the study. For example, people from Health Canada Health Products and Food Branch, (or) U.S. National Institutes of Health, (or) U.S. Food and Drug Administration, if necessary, may look at your records.”

“By signing this consent form, you agree to let these people look at your (your child’s) records. We will put a copy of this research consent form in your (your child’s) patient health records. We will give you a copy for your files.

“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. This could include external research team members. Following completion of the research study, the data will be kept as long as required and then destroyed as required by Sick Kids policy. Published study results will not reveal your identity.”

- For psychological research in which the results of tests may be of use for clinical purposes, the following paragraph should be added where appropriate.

“The results of the tests we describe in this form will be used only for this study. If another health care professional caring for you (your child) needs to see these results, you will have to give us your permission. We will ask you to sign a form saying that you agree that this person can see your (your child’s) results. We recommend that only a registered psychologist or doctor tell you what the results of these tests mean.”

- For research involving focus or support groups you should include the following statement verbatim:

“During the group meeting we will remind everyone that the information shared is private and should not be repeated outside the group. But we cannot be sure that information about you (your child) will be kept private. People in groups may share information about you with others outside the group.”

Reimbursement:

- Subjects or their parent/legal guardians must be offered money for reasonable out-of-pocket expenses; e.g. transportation costs, meals, baby-sitters, etc. In addition subjects, or their parent/legal guardians can be reimbursed for loss of wages (minimum wage). Under no circumstances should payment be offered for harm or discomfort. There is no predetermined limit for reimbursement, since research subjects expenses will vary depending on personal circumstances eg., distance from the Hospital. It should be clearly stated that if the subject withdraws from the research, there will be appropriate pro-rated reimbursement. (Please refer to the REB guidelines found on the REB website).

You should include the following sentence:

“We will reimburse you for all your reasonable out of pocket expenses for being in this study eg., meals, babysitters, parking and getting you to and from Sick Kids. If you stop taking part in the study, we will pay you for your expenses for taking part in the study up until that point.”

- Compensation, in recognition of time and effort may also be offered if matched appropriately with the age and mental capacity of the subject eg., guidance for appropriate compensation for a 12 year old may be taken from current fees for babysitting. To ensure transparency, information on compensation is also required in the consent & assent forms.

“We will also provide you with some compensation, [name item or monetary amount], in recognition of your time and effort.”

Participation:

- If there are parts of the research study which a research subject can choose not to participate in this should be clearly explained.
- One of 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 Sick Kids 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 Sick Kids will not be affected in any way by whether your child takes part in this study”.

- In those rare instances where it will not be possible for the subjects to withdraw (e.g. gene therapy), the limits on the right to withdraw should be carefully explained. There should still be a statement that the subject or his/her family will continue to have access to quality care at Sick Kids.

- The following statement must be included:

“New information that we get while we are doing this study may affect your decision to take part in this study. If this happens, we will tell you about this new information. And we will ask you again if you still want to be in the study”.

- Subjects should be made aware that they will not benefit financially from possible commercialization resulting from the research. The following statements must be included:

“During this study we may create new tests, new medicines, or other things that may be worth some money. Although we may make money from these findings, we cannot give you (your child) any of this money now or in the future because you (your child) took part in this study”.

- Parent/legal guardians of subjects should be made aware that assent may be required from their child.

- Because studies may be stopped early, the following statement must be included:

“In some situations, the study doctor or the company paying for the study may decide to stop the study. This could happen even if the medicine (or treatment) given in the study is helping you (your child). If this happens, the study doctor will talk to you about what will happen next”.

- The following statement must be included:

“If you (your child) become ill or are harmed because of study participation, we will treat you (your child) for free. Your signing this consent form does not interfere with your legal rights in any way. The study staff, any people who gave money for the study, or the hospital are still responsible, legally and professionally, for what they do.

Sponsorship:

- The following statements must be included: “The sponsor and/or funder of this research is

Conflict of Interest:

- It is the responsibility of the applicant to identify actual or potential conflicts of interest of members of their research team

- A declaration of any of the above should be made in the consent form, in language compatible with the following, and including all three of the aspects indicated (1. identity of the persons with the COI, 2. type of incentive or inducement, and 3. its source):

eg.,

“Some of the people doing this study have/may have a conflict of interest. That means that they may benefit personally, financially, or in some other way from this study.

1. Dr. X (name the investigator(s) and their roles in the present research), or a family member or dependent of Dr. X;
2. Has received or may receive for research related to the present study (money, or one or more of the following other benefits: speaker's fees, travel assistance, industry-initiated research grants, investigator-initiated research grants, consultant fees, honoraria, gifts, intellectual property rights such as patents, etc.);
3. From sponsor(s) that have activities related to the present study”

Or

“I, and the other research team members, have no conflict of interest to declare”

Consent :

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

“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 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 Sick Kids.
- 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 except as described to me.
- 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 for information on whom to contact in the event of injuries during a study, please call the Research Ethics Manager at 416-813-5718.

Research Ethics Board

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 Sick Kids.*
- 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 except as described to me.*
- 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.

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?
Please include the statement “If we feel your health may be in danger, we may have to report your results to your doctor”.
- 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

**Wording should be very simple. Sentences should use the active form at all times, and embedded phrases should be avoided. Larger font is recommended.*

Retention of signed research consent forms;

The research consent form and assent form are a permanent part of the health record.

1. In-patient subjects : For in-patients enrolled in a study, the research consent form and assent form are to be retained on the patient health record. This form should be kept in the research section of the in-patient blue binder.
2. Out-patient subjects : For out-patients enrolled in a study, the research consent form and assent form should be sent to Health Records Department. Health Records staff will add it to the subjects health record in the correspondence section.
3. Non-Sick Kids subjects :
 - a) For subjects who are patients at another institution, the research consent form and assent form are to be retained on that institution's health record.
 - b) For subjects who are healthy volunteers e.g., normal controls, or subjects in psychological research based at schools or in the community, the research consent form and assent form should be retained by the primary investigator in their research files.

The Public Hospitals Act requires that all parts of the health record be retained for ten years past the patient's eighteenth birthday, or ten years past the last hospital contact if the patient is over the age of eighteen.

- For studies involving in-patients and out-patients, Health Records will assume responsibility for retaining records in accordance with the law.
- For studies involving patients at other institutions, the investigator should ensure that the forms are retained on that institution's health record.
- For studies involving healthy volunteers, the investigator must retain the forms.