

PEDIATRIC CONSENT FORM (TEMPLATE)

*Red, italicized text is instructional, providing information to the consent form writer. It should be deleted when writing the consent form. The remainder of the text is mandatory, required by the Conjoint Health Research Ethics Board. This document is to be used as a template – cut text from your document and paste it into the appropriate sections in this one. Ensure the consent form is written in the second person through the whole document (including the compensation clause), except for the headings.*

*In the header or footer of every page insert the following information: Ethics ID, PI, Study Title, Version Number, Date, page expressed as page X of Y (specific/total).*

*An information sheet for children over the age of 7 should be attached to the consent form. The information sheet should be short (not more than two pages), simply written and age-appropriate. Describe what will be done to them and why, and explain that participation is voluntary. Please see the* [***CHREB Guidelines on Assent, Consent & Decision Making Capacity in Minors***](https://www.ucalgary.ca/research/files/research/chreb-guidelines-assent-consent-decision-making-capacity-in-minors-08aug2017.docx) *for more information.*

TITLE: *Insert the full title of the research project goes here.*

SPONSOR: *Put the name of the organization/company providing funds, drugs and/or equipment here.*

# INVESTIGATORS: *Include the name of the Principal Investigator followed by the names of any co-investigators.*

This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your child’s participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information. You will receive a copy of this form for your records.

## BACKGROUND

*This section of the consent form is for describing the rationale for the study and its design and methodology. It should state whether this research is a continuation of a previous study, increased dosage, changing administration of a drug, a new patient population, etc. Explain such aspects of research design as randomization and double-blind studies.*

*If the study is double-blinded, participants must be reassured that the blinding can be broken should an emergency arise and their treating physician require the information.*

*If deception is necessary for the research, debriefing is required and a description of the final consent process after debriefing needs to be explained here.*

*It is interesting for the subject to know how many subjects will be enrolled* *at how many health-care centres.*

## WHAT IS THE PURPOSE OF THE STUDY?

*Provide a description of the purpose of the study. Be concise, but avoid technical language and jargon that participants might not be familar with.*

## WHAT WOULD MY CHILD HAVE TO DO?

*Describe exactly what the research will involve for the subject. Include the frequency and number of each test, office visit or questionnaire. Estimate how much time these procedures may take, and if there is any follow-up. Inform the subjects how long the study is expected to continue, and how long they might be expected to participate. Identify those procedures that would not be a part of usual clinical care.*

* *Use bullets if they might help with clarity; and*
* *Use diagrams, charts or other illustrations if they would be useful. For example: flow charts of the sequence of events in the study or illustrations of medical equipment being used.*

## WHAT ARE THE RISKS?

*List all known side effects and risks of the study, and/or the testing required for the research in order of the severity and likelihood of potential harm. Canadian law stipulates that participants must be told about remote risks of severe harm, not just the more likely risks.*

## ARE THERE ANY BENEFITS FOR MY CHILD?

*Provide a conservative description of the probability and nature of direct and indirect benefits to the participants and to others.*

If you agree for your child to participate in this study there may or may not be a direct medical benefit to them. Their *name of disease* may be improved during the study but there is no guarantee that this research will help them. The information we get from this study may help us to provide better treatments in the future for patients with *name of disease*.

## DOES MY CHILD HAVE TO PARTICIPATE?

***Outline alternatives***

*If the study involves a disease or condition for which there are approved and/or standard treatments available, participants must be informed.*

***Voluntariness and Withdrawal of consent***

*Explain to the participant that participation in the study is voluntary and that they may withdraw from the study at any time without jeopardizing their health care (or education or employment as relevant). Tell the participant how they may withdraw, and explain any limitations to data withdrawal. Also, explain that the researcher can withdraw them from the study and reasons that might happen.*

*Inform participants that if new information becomes available that might affect their willingness to participate in the study, they will be informed as soon as possible.*

***Withdrawal of Study Data***

*Describe any circumstances that do not allow withdrawal of data or biospecimens once collected. Advise particpants that data cannot be withdrawn if they have been published or otherwise disseminated.*

## WHAT ELSE DOES MY CHILD’S PARTICIPATION INVOLVE?

*This is the section in which to describe any unique features of the research that have not already been discussed in the consent form and may affect the subjects.*

## WILL WE BE PAID FOR PARTICIPATING, OR DO WE HAVE TO PAY FOR ANYTHING?

*The CHREB is strongly disinclined to allow studies where participation in research means participants will incur costs.*

*Investigators are normally expected to reimburse or otherwise cover costs of parking for clinic visits that would not occur outside the context of the study.*

*See also the CHREB position statement on* [*payments to participants*](http://www.ucalgary.ca/research/files/research/160617-2016guideline_payment.pdf)*.*

*Do not use the word “compensation” in this section. Compensation for injuries is to be set out below under the separate heading.*

## WILL MY CHILD’S RECORDS BE KEPT PRIVATE?

*Explain who will have access to information collected and to whom, if anyone, the identity of the subject will be disclosed. Include how confidentiality will be protected. You may state that the University of Calgary Conjoint Health Research Ethics Board will have access to the records. For trials falling under FDA regulation, the following statement is mandatory:*

A description of this clinical trial will be available on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) as required by the U.S law. This Web site will not include information that can identify you or your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Authorized representatives from the University of Calgary and the Conjoint Health Research Ethics Board may look at your child’s identifiable medical/clinical study records held at (*name site*) for quality assurance purposes.

*(Other relevant organizations may include the Study Sponsor, Health Canada and/or other foreign regulatory agencies)*

*Please consider the potential for future uses of study data, and data sharing requirements, and advise participants of this possibility.*

*For example:* “Data collected during your child’s time in this research study will be de-identified and will be held in a database for future use by other researchers. Any future use of this research data is required to undergo review by a Research Ethics Board.”

## IF MY CHILD SUFFERS A RESEARCH-RELATED INJURY, WILL WE BE COMPENSATED?

*This is the compensation clause. There are certain circumstances where the compensation clause is not needed (e.g.: minimal risk research such as that involving questionnaires or interviews).*

*In clinical trials and procedures there must be a statement regarding possible compensation if the participant is injured as a result of the research. This section is not about legal liability, but is about whether the sponsor or researchers will voluntarily step up and cover any reasonable medical costs incurred that are not automatically covered by health insurance.*

*If the sponsor will not voluntarily provide compensation for research related injury, use this statement:*

In the event that your child suffers injury as a result of participating in this research, no compensation will be provided to you by *insert name of sponsor*, the University of Calgary, Alberta Health Services or the Researchers.You still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

#### *If the sponsor will provide compensation, use this clause:*

In the event that your child suffers injury as a result of participating in this research, *insert name of sponsor*, but not the University of Calgary, Alberta Health Services or the Researchers, will assist you by paying for any treatment or services your doctors recommend that is not covered by your health care insurance. Nothing said in this consent form alters your right to seek damages.

## SIGNATURES

Your signature on this form indicates that you have understood to your satisfaction the information regarding your child’s participation in the research project and agree to their participation as a subject. In no way does this waive your legal rights nor release the investigators, or involved institutions from their legal and professional responsibilities. You are free to withdraw your child from the study at any time without jeopardizing their health care. If you have further questions concerning matters related to this research, please contact:

Dr. \_\_\_\_\_\_\_\_\_\_\_ (403) \_\_\_-\_\_\_\_

or

Dr. \_\_\_\_\_\_\_\_\_\_\_ (403) \_\_\_-\_\_\_\_

If you have any questions concerning your rights as a possible participant in this research, please contact the Chair of the Conjoint Health Research Ethics Board, University of Calgary at 403-220-7990.

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| Parent/Guardian’s Name |  | Signature and Date |
|  |  |  |
| Child’s Name |  |  |
|  |  |  |
| Investigator/Delegate’s Name |  | Signature and Date |
|  |  |  |
| Witness’ Name |  | Signature and Date |
|  |  |  |

*Under ICH GCP (4.8.9), where it is known that the participant cannot read (e.g., visually impaired or illiterate), the signature of an impartial witness independent of the trial must be obtained. The witness must be present for the consent process. The witness signature reflects that they believe the participant was presented with sufficient information to assure a truly informed consent.*

The investigator or a member of the research team will, as appropriate, explain to your child the research and his or her involvement. They will seek your child’s ongoing cooperation throughout the study.

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

A signed copy of this consent form has been given to you to keep for your records and reference.

*Before submitting your consent form, please check it over for grammar, spelling and typing errors.*