GENERAL FORMATTING GUIDELINES FOR INFORMED CONSENT FORMS (ICF)

Please note that a well presented ICF that is in accordance to HREB standards will facilitate the approval process. ICFs that do not adhere to HREB standards will be returned to the researcher. Please adhere to the following formatting requirements:

1. Consent forms should be written at a Grade 6-9 level of understanding. Please use a readability index, such as hemingwayapp.com, to confirm the level.

2. Use plain language explaining medical terms and jargon. Use non-scientific terminology and remove emotive terms.

3. Type size should be no smaller than the type on this page. e.g. Times New Roman 12 point can be used.

4. Use headings, small paragraphs and spaces between the paragraphs

5. Regarding the use of DRUG TRADE NAMES in Consent Forms:
   Exclusive use of drug trade names in consent forms is not allowed. Acceptable forms of designation of drug names are: "*generic name*" or "*generic name (Trade name)" or define as "the study drug", "the study treatment"*
   Exception to 1: Where a drug product contains multiple ingredients which makes use of their generic names impractical, the trade name for the combination product may be used.

6. When reference is made to regulatory authorities having access to information please include Health Canada before other foreign regulatory agencies like FDA.

7. Write out and define all acronyms the first time they appear in the consent form.

8. Include a footer ON EACH PAGE with the Ethics ID (Pro number of your study) and version date of the site specific consent form and pagination (page 1 of X).

9. All information required by the participant must be included in the informed consent form (i.e., references to additional information found in ancillary drug information sheets is not acceptable).

10. Spelling, grammar and formatting must be corrected before it is submitted for review.

11. Use second person pronouns for the information letter part of the consent form (you/your). Use first person pronoun ("I") for only the final "consent statement" portion of the form.

12. Use 'participant' throughout the consent form rather than 'patient' or 'subject'.

13. Any parts of a study protocol that are optional should be separated out from the main consent, using a separate consent. There is too great a potential to have optional choices obfuscated and/or missed when presenting a series of options within the

main consent. Additionally, separating these out, truly conveys the optional nature of these activities, which differ from study mandated procedures.

Blue font: instructions
Black font: required language
Red font: insert as applicable or suggested language

In each section, replace the instructions (in blue) with information from your study. In some cases sample language is listed (in red), you may use this language, or replace with your own explanation. Any required language is listed in black. Throughout the consent form, use simple, non-technical terms, and address potential participants directly, with second-person language throughout.

To be on INVESTIGATOR Letterhead

CONSENT FORM FOR PARENT/GUARDIAN ON BEHALF OF CHILD PARTICIPANT

Title of Study:

Principal Investigator: *[include phone number]*

Many studies extend over a number of years and involve many investigators. To avoid the need to provide a revised consent form every time there is a change in co-investigators, it is acceptable to name the Principal Investigator only and to provide the full list of Co-investigators on the ethics application.

Research/Study Coordinator:

Why am I being asked to take part in this research study? *Describe, at a 6-9th grade reading level why this person might qualify for the research study. (i.e.* You are being asked to allow your child be in this research study because they have XX*) Also provide a brief explanation about why the research is being done so that the participant can understand why a particular health problem/intervention needs to be studied. For example, this can include non-technical information on the incidence of a disease, on the problems associated with a disease, on the poor outcomes for other treatment methods, etc.*

A brief statement about the "purpose" of the Information Sheet can be listed here, such as:
This form contains information about the study. Before you read it, a member of the study team will explain the study to you in detail. You are free to ask questions if there is anything you do not understand. You will be given a copy of this form for your records.

What is the reason for doing the study?
Describe the purpose of the study at a 6-9th grade reading level. Clearly state what the purpose of this SPECIFIC study is and what the study hopes to answer.

Key points to include in this section, when applicable, include the following:
- *Clearly explain what the standard treatment(s) is/are and why there is a need for the experimental intervention (ie the study rationale);*
- *If placebo controls are being used, explain why it is appropriate to use such controls;*

- *Indicate if the research is being carried out for the first time in humans;*
- *Include if study drug has approval in Canada for use in the disease under study,*
- *Indicate if the research is part of a larger multi-site clinical trial and when appropriate, also include the approximate number of participants in the study (overall and at this site).*

What will happen in the study? *The first part of this section should describe the study OVERALL, including the following information:*

- *how long each study visit will take and overall duration of the study;*
- *explain the difference between standard therapy and the study procedures;*
- *if participants will be assigned to different treatment arms – what this means and how will this be done.* Your child will be assigned at random, (like flipping a coin OR like rolling a dice), to one of *XX number* groups. He/she will have a *[specify 1 in 2, 3 in 4, 50%, etc]* chance of being in the group that receives Drug A and *[specify 1 in 2, 3 in 4, etc]* chance of being in the group that receives Drug B.
- *if the study is double blind – an explanation of what this is.* The study is double blind which means neither you nor your study doctor will know which treatment your child is getting. However, in the case of an emergency we can find out.
- *if applicable – a lay explanation of the use of a placebo arm.* A placebo is something that looks exactly the same as the study medicine, but does not have any real medicine in it.

THEN: Describe the procedures chronologically using simplistic language, short sentences (1-3) lines and short paragraphs (less than 6 sentences). The use of subheadings may help to organize the section and increase readability. Explain study procedures ONLY ONCE, and then represent what will happen at each study visit with a study chart of procedures – as opposed to repeating each procedure multiple times in different visit captions.

If pregnant women may be enrolled in the study: If your child is a female capable of becoming pregnant, a blood pregnancy test will be performed at the beginning of the study and must be confirmed negative. Urine pregnancy tests will be done during the study to confirm she is not pregnant while taking study drug. Since urine pregnancy testing is less sensitive than blood pregnancy testing (meaning it might not detect a pregnancy as early as a blood test), you can ask the study staff to have a blood pregnancy test done at any time.

Optional Studies

A separate section should be used to explain briefly about the availability of any optional studies that are not part of the main study and for which separate consent must be obtained, for example, tissue and blood banking studies, pharmacokinetic studies, use of individual data, records, or personally identifying information in another study, and analysis of secondary data from linked databases.

Recommended Text

The following studies are optional. For each optional study, you will be provided with a separate consent that describes the details, and which you will be required to sign if you wish to allow your child to participate. They can take part in the main study and not take part in

these optional studies. If you decide not to allow him/her take part in any or all of the optional studies, his/her care will not be affected.

What are the risks and discomforts? *Include information on any known risks or discomforts that may result from the study drugs and/or procedures that will be performed for the study, listing the most likely and/or most severe first.*

Give some context to the risks by grouping risks into those that are common, occasional or rare. QUANTIFY these GROUPINGS (i.e. common >50%, rare <1%). DO NOT USE a % after each individual risk. Ensure upper limits of risk ranges are provided – otherwise the participant will be told the upper limit is 100%

- *Explain the ramifications of some risks (for example, what is the importance to the participant if liver enzyme tests indicate an abnormality?);*
- *If animal data is provided by the Sponsor, its use should be minimized and attention drawn to the fact that its applicability to human participants is KNOWN or UNKNOWN.*
- *Any drugs and/or procedures that are given as standard of care do not need to be fully explained in the consent form. The risks should be limited to those that are related to the study interventions.*
- *Studies that present real and potential risks of fetal or reproductive harm should have a description of this risk. If reproductive risk exists, participants should be advised not to become pregnant (or to father a baby) while in this study.*
- *If the risk of fetal harm is not known, then indicate it is not known.*
- *If there are no risks associated with the research, then indicate no known risks.*

If applicable, add a statement that, There may be risks in this study that are currently not known. If we find out anything new during the course of this research which may change your willingness to allow your child to be in the study, we will tell you about these findings.

What are the benefits to me? *Describe any direct benefits to the participant first, followed by potential general benefits (e.g., to the group of patients to which the individual belongs, or to medical knowledge). If there is no anticipated direct benefit to the participant from the study, state this at the beginning of the section.*

Please note incentives such as cash, gift cards, and other material rewards are not considered benefits of participation, and should be included in the section "Will I be paid to be in the research?"

***Example**:* There will be no direct benefit to your child from participating in this study. However, this study will help the researchers learn more about [procedure/drug/intervention/device]. Hopefully this information will help in the treatment of future patients with [disease/condition].

What will we be asked to do while in the study? *This section is sometimes entitled "Subject Responsibilities", but should be entitled as above. List any specific requirements of the study that the participant must agree to comply with in order to participate (i.e., not taking certain medications, telling the study doctor of any adverse events within a certain amount of time). As well this section should list any specific instructions on avoiding becoming pregnant.*

What happens if my child is injured because of this research? *(Include this section only if more than minimal risk, or otherwise applicable)*

In the case of research-related side effects or injury, medical care will be provided by *specify response, e.g., your doctor or you will be referred for appropriate medical care.*

What are the rights of participants in a research study?

You will be told, in a timely manner, about new information that may be relevant to you/your child's willingness to stay in this study. You/your child's rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that you/your child's privacy is respected.

By signing this form you do not give up any of you/your child's 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.

Do I have to agree for my child to take part in the study? *This section should stress the voluntary nature of the study.* Being in this study is your choice. If you decide to allow your child to be in the study, you can change your mind and stop being in the study at any time, and it will in no way affect the care or treatment that your child is entitled to.

Withdrawal of consent
The consent form must clearly describe what happens upon withdrawal, including options for continued safety follow-up and study-related access to medical records, and the handling of data and samples already collected. This must match what has been outlined in the protocol and ethics application. Your child can stop being in the study at any time, and this will not affect the care your child is entitled to receive. If you decide you wish to stop, the study team will go over your child's options with you and will document your decision in the study record. You do not need to sign anything to stop being in the study.

Can our participation in the study end early? *(Include only if applicable) Describe in lay terms any reason why a participant may be removed from the study, i.e.*, In addition to you being able to stop being in the study at any time, the study doctor or the sponsor of the study *(if applicable)* may withdraw your child from this study (*list reasons why here* i.e. if you don't show up for study visits, if they feel it is in your child's best interest, if the approval for the study is withdrawn…etc).

Are there other choices to being in this research study? *Ensure that the participant understands clearly what treatment/options they would have if they were not in the study:* You do not have to allow your child to join the study in order to receive treatment. The study doctor will explain other treatment options to you in detail. *If there are no alternatives to treatment, then you do not need to state that the option is to NOT participant. Just leave this section out.*

What will it cost to participate? *(Include only if applicable) A clear statement must be made about any costs for participation in the study. The REB is strongly disinclined to allow studies where participation in research means participants will incur costs.*

Will we be paid to be in the research? *(Include only if applicable) A clear statement must be made about any reimbursement the participant will receive for being in the study (i.e. parking costs, food, $$ for time, extra credit etc.) Be sure to indicate if these amounts are to be pro-rated for study visit completion.*
NOTE: The HREB will take into consideration the nature and amount of compensation (i.e., the compensation alone should not serve as sufficient inducement for the participant to volunteer).

INCLUDE IF APPLICABLE: If you receive more than $500 in compensation or incentives for participating in this study within a calendar year, the University of Alberta *[NOTE: EDIT AS REQUIRED or other financial administration office ie AHS, Covenant, third party vendor depending on your study]* is required to issue you a T4A slip for tax purposes to comply with Canada Revenue Agency (CRA) regulations. This means that the study team may have to collect information about you such as your first and last name, date of birth, address and potentially your Social Insurance Number (SIN). You can decline payment for this study and still participate in the study if you choose.

If the University of Alberta holds the account for your study: Your personal information will be securely stored by the University of Alberta and used only for tax reporting purposes.

Privacy and Confidentiality

During this study we will be collecting information (or "study data") about your child. We will use the data to help answer research questions and we will share (or "disclose") your child's information with others such as the study sponsor and other researchers. Your child's study data may also be shared with government departments involved in the approval of drugs for sale in a country. These departments are often called "regulatory authorities". An example of a regulatory authority is Health Canada.

Below we describe in more detail how your child's data will be collected, stored, used and disclosed.

What data will we be collecting?

During this study we will be collecting data about your child. Examples of the types of data we may collect about your child includes his/her: name, address, ethnic background, date of birth, age, health conditions, health history, medications and results of tests or procedures that he/she may have had. We will only look for and collect the information that we need do the research. We will get this information by asking you and/or your child questions and doing the tests outlined in this form. We will also look at his/her medical chart (paper or electronic) held by the study doctor or other doctors they have seen (such as their family doctor).

How will the study data be stored?

The study data we collect which will include your child's name will be securely stored by the study doctor during and after the study. We will also put a copy of this consent form in your child's clinical record, so that doctors you see in the future will know your child was in the study. In Canada, the law says we have to keep the study data stored for at least 15 years after the end of the study.

The study doctor will not release your child's name to anyone unless the law says that they have to.

How will the study data be used? *{Modify as needed for study – if you will be sending any data which contains any element which per AHS data standards would constitute an identifier this needs to reflect that identifiable data will be sent to the Sponsor}*

Your child's study data will be coded with a unique identifier, removing direct personal identifiers such as your child's name and address to protect their privacy. However, it is important to note that full dates, such as date of birth or date of hospital admission may be considered identifying information (for example, per AHS standards). Therefore, while your child's data will be coded, the inclusion of full dates could still make it possible, under certain circumstances, to trace the data back to your child. Only the study doctor will be able to associate your child's coded study data to their identity.

The coded study data will be sent to the Sponsor. This coded study data will be kept by the Sponsor in a secure manner and will be used now and in the future to:

- learn more about how the study drug (and possibly similar drugs) works and how safe it is;
- learn more about how to treat this disease and other similar diseases;
- apply for get approval to sell the study drug in Canada or other countries;

This coded study data may also be shared with people who work with the Sponsor and with regulatory authorities. The Sponsor and/or the people they work with may be located outside of Canada, in countries that do not have the same privacy laws as in Canada. However, because nothing that is sent to the Sponsor will contain your child's name, no one who uses this information in the future will be able to know it came from him/her. The risk to your child's privacy, then, should be very small.

When the study is done, the Sponsor may place your child's coded study data into a secure database. The coded data may then be used to answer other research questions in the future. Only researchers who have the training and experience to do the research (also known as "qualified researchers") will be allowed to use the data. *{State whether or not data will be anonymized (i.e. No way to link back to individual ever) or de-identified (link remains at study site) and state how long it will be stored for future use.}*

Who will be able to look at my child's health data?

During research studies it is important that the data we get is accurate. Therefore, your child's study data and original medical records may also be looked at by people from: the study sponsor, the University of Alberta auditors and members of the Research Ethics Board, Health Canada, and/or other foreign regulatory authorities.

By signing this consent form you are saying it is ok for the study doctor/staff to collect, use and disclose information from your child's medical records and his/her study data as described above.

If you would like to see the study data collected about your child, please ask the study doctor. You will be able to look at the study data about your child and you can ask for any mistakes to be corrected. The study doctor may not be able to show you your child's study data right away and you may have to wait until the study is completed or another time in the future before you can see his/her study data.

If you leave the study, we will not collect new health information about your child, but we will need to keep the data that we have already collected.

What if I have questions?
If you have any questions about the research now or later, or if your child experiences any adverse effects, or you think that your child has suffered a research related injury please contact *[enter Investigator and/or study coordinator numbers here]. For greater than minimal risk, include 24 hour night/emergency phone numbers.*

If you have any questions regarding your child's rights as a research participant, you may contact the University of Alberta Research Ethics Office at reoffice@ualberta.ca. This office is independent of the study investigators.

Researchers must disclose:
• Any actual or potential conflicts of interest involving themselves, study staff, or their immediate family members.
• Any financial payments or benefits beyond typical academic or professional recognition (e.g., speaking fees, consulting income, patent rights).
• Who is receiving the benefit, what kind it is, and where it comes from.
You must also explain any institutional funding for the study, even if no individual conflict exists.

The study is being funded by *[name of funder/granting agency or commercial sponsor].* This means that the Institution and researchers are getting money from the granting agency/funder to cover the costs of doing this study. This funding does not involve any personal payments to the research team. OR You are entitled to request any details concerning this funding from the researcher.

How do I indicate my agreement to be in this study?

By signing below, you understand:

- That you have read the above information and have had anything that you do not understand explained to you to your satisfaction
- That your child will be taking part in a research study
- That your child may freely leave the research study at any time
- That you do not waive any legal rights by being in the study

- That the legal and professional obligations of the investigators and involved institutions are not changed by taking part in this study.

I agree to allow my child _____ to take part in this study.
(CHILD's NAME)

SIGNATURE OF PARENT OR LEGAL GUARDIAN

I have the legal authority to give this consent.

Signature of Parent or Legal Guardian _____

(Printed Name) _____

Date:_____

SIGNATURE OF PERSON OBTAINING CONSENT

_____
Signature of Person Obtaining Consent

_____ _____
Name of Person Obtaining Consent Date

SIGNATURE OF THE WITNESS

_____
Signature of Witness

_____ _____
Name of Witness Date

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