Appendix F

Parent/Guardian’s consent form for participants
under 16 years of age, or in Quebec 18 years of age

Note to Researcher
This parent/guardian consent form should accompany the Child’s Assent form for the individual under 16-18 years of age.

The child should provide his/her assent and may refuse to participate even if the parent has provided their consent. The age of consent to participate in research in the Province of Quebec is 18 years of age. Section 21 of the Quebec Civil Code should be referenced for additional information as to the involvement of children in research. The Assent form for the involvement of minors in research should be used for any individuals under the age of 18.

Informed Consent Template

Title of Research Project:
• The title name must be the same as the one provided on Page I of the Application Form.

Investigator(s):
• Include the name and telephone number of all investigators.

Purpose of the Research:
This section should answer the question: “Why do the study?”
• Provide a brief description of the purpose of the study.

Description of the Research:
This section should answer the questions: “How will the study be conducted and how will my child be involved?”
• Mention that this is an invitation for the child to participate in this study.
• Provide a brief step-by-step description of the proposed research as it will be experienced.
by their child in this research study. Be sure to distinguish between those interventions that are part of standard therapy and those that are research.

- If the child is required to undergo specific testing as part of the research, this must be explained to the parent or guardian (for example, HIV testing).

- If the child is receiving any therapy prior to enrollment in the study and this therapy will or may be altered or discontinued as a result of participation in the study, this must be explained to the parent or guardian.

- If randomization or sequential assignment is to be carried out, this must be explained to the parent or guardian.

- If blood will be taken from the child, indicate total volume (for example, teaspoons and ml equivalents) and a statement about the possibility of bruising or swelling while giving blood, or some other discomforts at the site where blood is drawn from the child and that there may be minimal chance of infection, and that these discomforts are brief and transient.

- If a questionnaire is to be completed by the parent/guardian or the child, provide a description of the questionnaire, how long it will take to complete and that the participants have a choice of not answering any questions or withdrawing at any time.

- Indicate frequency and duration of specific testing, as well as the duration of the entire study.

- Include the following statement “If changes are made to the study or new information becomes available, you will be informed”.

- If future use of the research data beyond the current study is anticipated, this should be explained. 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, this requires to be indicated in the consent form.

**Access to Research Information:**

- Information regarding who will have access to the data collected.

- Information regarding retention of data (including audio and video tapes) and schedules for their disposal.
• How, if at all, participants will be informed of the results of the research.

• Indicate on the consent form that “your child may refuse to participate or may withdraw at any time”. If the participant withdraws, can the participant remove his/her data from the collection undertaken in this research project? If yes, please indicate this on the consent form. If not, the researcher will be required to provide a rationale for not providing the participants with a choice of removing his/her data from this research and any future research.

• If future research projects are anticipated, there is a need to seek the participants’ consent to allow their data to be used for future research projects, by inserting this question on the consent form: Do you agree for your child’s samples to be used for future research?
  • Yes    No   (if they say no, then you may not retain the samples for future research projects)

Potential Harm Injuries, Discomforts or Inconvenience:
• If there is no known harm to the child, this should be stated in the following way: “There is no known harm associated with your child participating in this study”.

• If there is known harm to the child, the parent/guardian should be informed of:
  a) the potential harm;
  b) current knowledge regarding the probability of the occurrence of the harm;
  c) clinical importance of the harm; and
  d) any relevant knowledge regarding the probability of reversibility; for example, if blood is taken, provide a statement about the possibility of bruising or swelling while giving blood, or some other discomforts at the site where blood is drawn and that there may be minimal chance of infection, and that these discomforts are brief and transient.

Potential Benefits:
• If the child will not benefit directly from participation in this study, the following statement should be included: “Your child will not benefit directly from participating in this study.”

• If the child may benefit directly from participating in this study, this should be stated and potential benefits should be described.

• 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 child.
Treatment Alternatives:

- If there is no treatment alternative (for example, no available therapy), the alternative to participation in the study is non-treatment and this should be explained.

- If there is/are treatment alternative(s), 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 statement regarding confidentiality will be applicable to most studies and should be included: “Confidentiality will be respected and no information that discloses the identity of your child will be released or published without your consent unless required by law.” (For example, this legal obligation may include a number of circumstances, such as: suspected child abuse, infectious disease, expression of suicidal ideas where research documents are ordered to be produced by a court of law and where researchers are obliged to report to the appropriate authorities.)

- If access is required by a sponsor or a regulatory authority, the above statement should be replaced with the following: “Confidentiality will be respected and no information that discloses the identity of your child will be published without your consent unless required by law. However, records identifying your child may be given to and inspected by HC/PHAC senior officials and the REB members, for the purpose of monitoring the study.”

- In those rare instances where it will not be possible to assure complete confidentiality, the limits on this obligation should be carefully explained (for example, Focus Groups, suspected child abuse).

- For Focus Groups, the Principal Investigator should consider adding a statement of the potential harm that could exist if confidentiality is violated by someone participating in these focus groups. The researchers are required to explain the two kinds of confidentiality that may apply in this situation: 1) the researchers are capable of promising confidentiality of information but 2) can’t promise that the other participants will observe each others privacy.

Reimbursement:

- Children or their parents/guardians can be offered money for reasonable out-of-pocket expenses; (For example, transportation costs, meals, baby-sitters, etc.). In addition, the parent and/or guardian can be reimbursed for loss of wages (minimum wage). Under no circumstances should payment be offered for harm or discomfort.
• It should be clearly stated that if the participant withdraws from the research, there will be appropriate pro-rated reimbursement.

• A thank-you gift may be presented after completion of the study, but this should not be mentioned in the research consent form.

• If the study is a randomized trial both arms of the study should be equally reimbursed unless there is a clear direct benefit to one group of participants.

**Participation:**

• If there are parts of the research study in which the child could choose not to participate this should be clearly explained to the parent/guardian.

• The following statements must be included: “Participation in research is voluntary. If your child chooses to participate in this study, your child may withdraw at any time.”

• If they do not wish to participate, they do not have to provide any reason for their decision not to participate nor will they lose the benefit of any medical care to which they are entitled or are presently receiving;

• In those rare instances where it will not be possible for the child to withdraw (for example, gene therapy) the limits on the right to withdraw should be carefully explained to the parent/guardian.

• Parent and/or guardian of the child should be made aware that assent is required from their child, if the child is of age to understand their participation in the research.

• The parent and/or guardian of the child must be given a copy of the consent form to keep.

**Waiver of Rights:**

• Investigators are prohibited from seeking or obtaining waivers of participant’s legal rights.

**Voluntariness:**

• The following statements must be included: “Participation in research is voluntary. If you choose on behalf of your child to participate in this study you can withdraw your child from the study at any time.”

**Contact:**

If you have any questions about this study, please contact:

Date:
Version:
Name, area code and phone number of Investigator
Collect calls will be accepted

If you have questions about your child's rights as a research participant, you may contact:
Manager, Research Ethics Board Secretariat
70 Colombine Driveway
9th Floor, Room 941C
Brooke Claxton Building, Postal Locator: 0909C
Tunney’s Pasture
Ottawa, Ontario, K1A 0K9
Phone number (613) 941-5199
Fax (613) 941-9093
Email: REB-CER@hc-sc.gc.ca

Consent:

By signing this form, I agree that:

- The study has been explained to me and my child. Yes ☐ No ☐
- All our questions were answered. Yes ☐ No ☐
- The possible harms and discomforts and the possible benefits (if any) of this study have been explained to me and my child. Yes ☐ No ☐
- I understand that I have the right not to have my child participate and the right to stop his/her participation at any time. Yes ☐ No ☐
- I understand that I may refuse to have my child participate without consequence Yes ☐ No ☐
- I have a choice of having my child not answer any specific questions. Yes ☐ No ☐
- I and my child are free now, and in the future, to ask any questions about the study. Yes ☐ No ☐
- I understand that there may be a very slight risk to my child while giving blood and that there may be minimal chance of infection. These discomforts are to be brief and transient. Yes ☐ No ☐
- I have been told that my child's personal records will be kept confidential. Yes ☐ No ☐
- I understand that no information that would identify my child will be released or printed without asking me first. Yes ☐ No ☐
- I understand that I and my child will receive a signed copy of the consent form.
For future research projects: (if applicable)

- I agree that my child’s data/blood samples may be used for future testing in similar research projects.

I hereby consent to have my child participate in this study:

______________________________ __________________
Signature Date

Name of Child: _________________________________

Name of person who obtained consent: _________________________________

______________________________ __________________
Signature Date