Appendix G
Children’s Assent (Consent form for participants under 16 years of age, 18 years of age in Quebec)

Note to Researchers
For parents of participants under 16 years of age, a separate consent form must be included with this form, please see Parent/Guardian’s Consent Form.

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.

Language level of this assent form must not be any higher then grade 6 reading level. (Use a Microsoft Word software to determine the language level of the form)

Assent Form 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 the child be involved?”

- Mention that this is an invitation to participate in this study.

- Provide a brief step-by-step description of the proposed research as it will be experienced by the child.

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

- If the child is receiving any therapy prior to enrolment in the study and this therapy will or may be changed or discontinued as a result of participating in the study, this must be explained.

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

- If blood will be taken, indicate to the child the total volume of blood to be taken (for example, teaspoons and ml equivalents) and include a statement on possible bruising or swelling, and that there may be minimal chance of infection, that these discomforts are brief and temporary.

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

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

- 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 after the current study is anticipated, this should be explained (for example subsequent use of videos, DNA banking, creation of a permanent cell line). If the research data/samples are to be destroyed after the study is completed, this should be explained. If participants do not agree on the consent form to have their samples to be used for future research, then you may not retain the samples for future research projects.
If the study involves taking photographs, videotaping or sound recordings, this should be referenced in the consent form.

Access to Research Information:
- Information regarding who will have access to the data collected on the child.
- Information regarding the retention of the child’s data (including audio and video tapes) and when it will be destroyed.
- If applicable, explain how the child will be informed of the results of the research.
- Indicate on the consent form that “you may refuse to participate or may withdraw at any time”. If the participant withdraws can the child remove his/her data from the collection? If yes, to 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.
- A paragraph should inform the child that “If we feel your health may be in danger, we may have to report your results to your doctor”.

Potential Harm Injuries, Discomforts or Inconvenience:
- If there is no known harm to the child, this should be stated in one of the following ways: “There is no known harm associated with you participating in this study.”
- If there is known harm to the child state clearly:
  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, a statement about the possibility of bruising or swelling while giving blood, and that there may be minimal chance of infection, that these discomforts are brief and temporary.”
- The likely consequences of non-action should be clearly explained.
- Information on adverse events must be reported immediately to the Research Ethics Board (REB) and may require revisions to the consent and assent forms.

Potential Benefits:

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• If the child will not benefit directly from participating in this study, the following statement should be included: “You 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 your identity will be released or published without your consent.”

  • If access is required by a sponsor or a regulatory authority, the following statement should be replaced with the following: “Confidentiality will be respected and no information that discloses your identity will be published without your consent. However, records identifying the participant may be given to and inspected by HC senior officials and 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 may be offered money for out-of-pocket expenses; (For example, transportation costs, meals, etc.). Under no circumstances should payment be offered for harm or discomfort.

- It should be clearly stated that if the child withdraws from the research, there will be appropriate 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 sides 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 a child could choose not to participate this should be clearly explained.

- The following statements must be included: “Participation in research is voluntary. If you choose to participate in this study you can 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.

- 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 child’s legal rights.

Voluntariness:
- The following statements must be included: “Participation in research is voluntary. If you choose to participate in this study you can withdraw 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. [ ] Yes [ ] No
- All my questions were answered. [ ] Yes [ ] No
- The possible harms and discomforts and the possible benefits (if any) of this study have been explained to me. [ ] Yes [ ] No
- I understand that I have the right not to participate and the right to stop at any time. [ ] Yes [ ] No
- I understand that I may refuse to participate without any problems. [ ] Yes [ ] No
- I have a choice of not answering any specific questions. [ ] Yes [ ] No
- I am free now, and in the future, to ask any questions about the study. [ ] Yes [ ] No
- I understand that there is a very slight risk while I give blood and that there may be minimal chance of infection. These discomforts are brief and temporary. [ ] Yes [ ] No
- I have been told that my personal records will be kept confidential [ ] Yes [ ] No
- I understand that no information that would identify me will be released or printed without asking me first. [ ] Yes [ ] No
- I understand that I will receive a signed copy of this consent form. [ ] Yes [ ] No

For future research projects: (if applicable)
- I agree that my data may be used for future testing in similar research projects. [ ] Yes [ ] No

I hereby consent to participate.

________________________________________  ______________________
Signature                                  Date

Name of Child Participant: _____________________________________________

Name of person who obtained consent: ____________________________________

________________________________________  ______________________
Signature                                  Date

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