## A Letter with New Information

Title:
Protocol Title:

**Addendum # 1 to the Patient Informed Consent, Version (fill in date of most recent approved consent)**

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You have signed consent to take part in this study. This letter provides new information that we have learned since this study started.

***Add new information here. Describing to the patient how this information has changed from the start of the study and why***

You can also talk to someone who is not involved with the study at all. They can tell you about your rights as a participant in a research study. This person can be reached through:

**Ethics Office at 709-864-8871**
Email: info@hrea.ca
Web: www.hrea.ca

*All other information from the main consent remains unchanged.*

*By signing this form, you are indicating that you have read and understand this information, and that you agree to continue to take part in this study.*

| | | |
|---|---|---|
| Signature of Participant | Printed Name | Date |
| Signature of person authorized as substitute decision maker (if applicable) | Printed name | Date |
| Signature of Witness (if applicable) | Printed Name | Date |

Protocol #
Version Date Initial_____

# Signature Page for Parent/Guardian

I consent for my child/ward _____to take part in this study.

| _____ | _____ | _____ |
|---|---|---|
| Signature of parent/guardian | Name (printed) | Date |
| _____ | _____ | _____ |
| Signature of person conducting the consent discussion | Name (printed) | Date |
| _____ | _____ | _____ |
| Signature of witness (if applicable) | Name (printed) | Date |

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I believe that the person signing this form understands this new information and voluntarily agrees to continue to participate.

| _____ | _____ |
|---|---|
| Signature of Investigator | Date |

**To be signed by the minor participant [if appropriate]**
**Assent of minor participant:**

**I understand the purpose of this research**
**I understand that it is my decision to take part in this study. I can stop taking part if I chose.**
**I understand that taking part in this research may not help me.**
**I understand that there may be risks to participating in this study.**

I agree that I will take part in this study

Signature of minor participant Date

Name printed Age

**Participant Assistance**

**Complete the following declaration only if the participant is unable to read:**

- The informed consent form was accurately explained to, and apparently understood by, the participant, and
- Informed consent was freely given by the participant

Signature of Impartial Witness | Printed Name | Date

**Complete the following declaration only if the participant has limited proficiency in the language in which the consent form is written and interpretation was provided as follows**:

- The informed consent discussion was interpreted by an interpreter and
- A sight translation of this document was provided by the interpreter as directed by the research staff conducting the consent.

**Interpreter Declaration and Signature:**
By signing the consent form I attest that I provided a faithful interpretation for any discussion that took place in my presence, and provided a sight translation of this document as directed by the research staff conducting the consent.

Signature of Interpreter | Printed Name | Date