# Received Date

REB Use Only



## **Baycrest Research Ethics Board**

### Amendment Form

Do not leave any box blank. Indicate “not applicable” by typing N/A. Submit typed, hard copy of this form with original signature to the REB office for review. See the Guidelines for Submitting Amendment and/or Administrative Change for more information.

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| Study Identification |
| Principal Investigator:  | REB Number:  |
| Study Title:  |
| Sponsor:  |
| Department/Division: Telephone:  |
| Fax: Email:  |
| Name of Person Completing Form: Telephone:  |
| Fax: Email:  |
| **Amendment Review Information** |
| Indicate type of change: [ ]  Amendment [ ]  Administrative ChangeHas this amendment already been implemented to eliminate an immediate hazard? 🞏 Yes 🞏 NoThis request will be expedited unless the Chair determines that it is necessary to go to the full REB for review. |
| Indicate documents submitted with this form**:****Note: (1) The date (mm/dd/yyyy) and Version # must be on every page of all documents. Revisions will not be accepted without dates and version numbers. (2) If you have made changes to the informed consent form (ICF) since its last REB approval, you must provide details and/or the rational for the changes in the "Amendment Detail" box below as well as highlight the changes (bold, underline or track-it) on the ICF form.**  |
| [ ]  Version #: Date: Version: | [ ]  Recruitment Tools (advertisements, websites, letter of introduction etc.) Date: Version: |
| [ ]  Revised Protocol Date: Version: | [ ]  Informed Consent Form(s) Date: Version: |
| [ ]  Documentation summarizing rationale and change(s) Date:[ ]  Attached [ ]  See page 2 | [ ]  Questionnaires, Surveys, Interview Scripts, Diaries, etc. Date: Version: |
| [ ]  Informed Consent Form (s) Date: Version: | [ ]  Investigator’s Brochure Date: Version: |
| [ ]  Addendum to Consent Form(s) Date: Version: | [ ]  Communication Tools (newsletters, medication  instructions, etc.) |
| [ ]  Assent Form(s) **(used where participant is unable to consent; documentation is required to indicate his/her assent)** Date: Version: | [ ]  Other |

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| Amendment Details |
| 1. Provide justification/rationale for the change(s) and identify any change(s) made on the attached documents (e.g. flyer, informed consent form. |
| 2. If study participants need to be informed of changes related to the amendment, describe how and when they will be informed. |
| 3. Provide the following information if study involves investigational drugs or devices. [ ]  Not Applicable1. Does this study involve any of the following (check all that apply):

[ ]  Investigational new drugs[ ]  Investigational biologics[ ]  Investigational natural health products (NHP)[ ]  Investigational medical devices[ ]  Approved drug for a new indication (e.g., new age-group, disease entity)1. If the amendment involves any of the above:

 Is a “No objection” or authorization letter from Health Canada attached? [ ]  Yes [ ]  No If no, has, or will, a Clinical Trial Application (CTA) been submitted to Health Canada? [ ]  Yes [ ]  No If pending, provide date of submission: Health Canada “No objection” file number: If “No objection” letter or authorization is pending, forward approval letter to the REB office as soon as it is available.1. Provide FDA IND number (drug studies) or PMA number (device studies):

[ ]  Not Applicable[ ]  Pending (if pending, forward to the REB office when available)  |
| Principal Investigator SignatureThis signature attests that the PI accepts the amendment/administrative change. For amendments, the PI’s signature further attests that the PI has assessed the safety implications of the amendment, its impact on study procedures and is prepared to take all necessary steps to implement the change.Print Name: Signature:  Date: / /  (DD/MM/YYYY) |