**\*Refer to the Amendment Request Instructions and**

**Policy REB-409 before completing this form.\***

|  |
| --- |
| REB#:       |
| Project Title:       |
| Local Principal Investigator (LPI):       |
| Today’s Date:       |
| Study Approval Expiry Date:       |

1. Identify all areas being amended. **Please submit one clean copy and one tracked changes copy of all modified study documents.** If submission of a tracked changes copy is not feasible, please attach a summary of changes.

|  |  |
| --- | --- |
| **Protocol** | **Information/Consent Process** |
| [ ]  | Research question/study objectives | [ ]  | Informed Consent Form |
| [ ]  | Study protocol or design | [ ]  | Capacity assessment |
| [ ]  | Study measures or questionnaires | [ ]  | Assent form or guidance document |
| [ ]  | Study title | [ ]  | Consent or assent process |
| [ ]  | Duration of study  | [ ]  | Process for withdrawal of consent |
| [ ]  | Local PI and/or other investigators |  |
| [ ]  | Funding agency | **Recruitment** |
| [ ]  | Number of participants[ ]  Local [ ]  Global | [ ]  | Recruitment materials |
| [ ]  | Participant recruitment process |
| [ ]  | Inclusion/exclusion criteria  | [ ]  | Invitation letter |
| [ ]  | Compensation for participants  |  |
| [ ]  | Potential risks and/or benefits | **Other (please describe)** |
| [ ]  | Procedures/safeguards to minimize risk | [ ]  |       |
| [ ]  | Procedures to ensure confidentiality  | [ ]  |       |
| [ ]  | Vulnerability of participants | [ ]  |       |
| [ ]  | Case report forms/data collection forms | [ ]  |       |

1. Current status of the study. Check all that apply:

[ ]  Participant enrollment has not started

[ ]  Enrolling participants/collecting data

[ ]  Enrollment complete and follow-up continues

[ ]  Follow-up complete and data analysis continues

[ ]  Other (describe)

1. Describe and provide justification for each amendment.

1. Could greater discomfort, inconvenience, vulnerability, or risk of harm (physical, psychological, economic or social) to participants or others follow the introduction of amendments? Yes [ ]  No [ ]

If yes, describe the probable impact of the proposed amendment(s) on these factors:

1. Is the proposed amendment a result of an adverse event or other unanticipated problem?

Yes [ ]  No [ ]  If yes, submit an *Unanticipated Problem Report Form* as per Policy REB-407.

1. Is the proposed amendment a result of a protocol deviation?

Yes [ ]  No [ ]  If yes, submit a *Protocol Deviation Report Form* as per Policy REB-406.

1. Does the proposed amendment add a new or alter an approved study objective?

Yes [ ]  No[ ]

If yes, explain why the change is presented as an amendment, rather than submitted as a new study.

1. Does the proposed amendment result from new information that might influence a participant’s willingness to continue in the study?

Yes [ ]  No [ ]

If yes, explain.

1. Does this Amendment require a submission to Health Canada?

 [ ]  Yes ; please specify:

 [ ]  N/A OR [ ]  No ; please explain:

If yes, please provide the REB with a copy of the applicable Health Canada authorization (e.g., No Objection Letter; Acknowledgement of Notification)

1. Could the proposed amendment affect the value of the study data collected to date?

Yes [ ]  No [ ]

If yes, describe and justify the continuation of the study.

1. What follow-up action do you propose, once the amendment is implemented, for participants who are already enrolled in the study?

[ ]  Inform study participants

[ ]  Re-consent all participants with the revised consent/assent forms

[ ]  No action required

[ ]  Other action (specify)

1. Please list all documents submitted with the amendment: N/A [ ]

|  |  |  |
| --- | --- | --- |
| Title of ‘Clean’ Documents Submitted | Version # | Version Date |
|       |       |       |
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***Local Principal Investigator Signature***

As Local Principal Investigator, I assume responsibility for the scientific and ethical conduct of this amended study. I agree to conduct this study in compliance with the 2nd Edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans and, where required, in accordance with Health Canada regulations, Good Clinical Practices, and regulations in other jurisdictions.

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Signature Date

**For REB Use Only**

[ ]  Amendment Request approved as submitted.

[ ]  Amendment Request conditionally approved.

Conditions:

[ ]  Amendment Request requires revision and resubmission. The following additional information and/or revisions are required for REB review:

[ ]  Study suspended pending further review.

Rationale:

[ ]  Amendment(s) denied:

Rationale:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of REB Chair (or Designate)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date