**TRILLIUM HEALTH PARTNERS RESEARCH ETHICS BOARD (REB)**

**AMENDMENT SUBMISSION FORM**

**REB Study ID#**

| \* If there is a change to study personnel, please complete Change in Investigator/Study Personnel form |
| --- |

Date form submitted:

Expiry date of current REB approval:

**CONTACT INFORMATION**

1. Person completing this form:

| Title: | Name: |
| --- | --- |
| Department/Division: | Institution: |
| Telephone: | E-mail: |

1. **STUDY DETAILS**
2. Full study title:
3. Please provide a summary of the study suitable for a lay audience:

| 1. Current REB approved protocol version and date: |  |
| --- | --- |
|  |  |
| 1. Current REB approved consent version and date: | N/A |

1. Enrollment status (*for retrospective and prospective chart reviews, enrollment would be the number of patients whose charts were accessed*):

| Open to Accrual  Closed to Accrual |
| --- |
| Study involves recruitment only at THP |
| Number of patients enrolled at THP to date *[specify per site (CVH, MH, and Q), if applicable)*: |

1. Are there currently any patients in follow-up?

Yes  No  N/A

1. **AMENDMENT DETAILS**
2. Documents being amended or added *(Ensure a clean and a tracked change version of all amended study documents are attached with your amendment submission package):*

| Protocol | Thank you letter | Consent Form(s) |
| --- | --- | --- |
| Data Collection Form(s) | Questionnaire/Survey | ☐ Recruitment material |
| ☐ Investigator's Brochure | Interview/Focus Group Script | Other (please specify): |

1. Version and date of document(s) being amended or added:
2. Type of amendment(s) please select all that apply:

| Study Procedures | Data Collection Period | Updated Product Monograph |
| --- | --- | --- |
| Study Site | Number of Groups/Arms | Recruitment Process |
| Sample Size | Inclusion/Exclusion Criteria | Administrative Change |
| Data Source | Amount of Funding required | Consent Model/Process |
| Study Sponsor | Screening Sample Size | Funding Source |
| Data Collection | Patient Reimbursement | Updated Risk/Benefit Profile |
| Length of Study | Updated Investigator Brochure | Other (please Specify): |

| Additional (please Specify): |
| --- |

1. Amendment summary *(Describe the change(s), the justification/rationale for each change and if and how study patients will be informed of the change(s), if applicable):*
2. Does the amendment require authorization from Health Canada (No Objection Letter, Notice of Authorization, and Investigational Testing Authorization)?

Yes – attached  Yes – pending  No  N/A

1. **ADDITIONAL COMMENTS/NOTES**

1. **RESOURCE IMPACT**
2. Are there additional impact(s) on any supporting department(s)?

Yes  No  N/A

* 1. If yes, which department(s)?
  2. If the amendment(s) place additional impact(s) on any supporting departments, please inform the affected department of any changes that may impact them and submit a resource impact form with the signature of approval for this amendment from the appropriate department/division signatory to [ResearchOperations@thp.ca](mailto:ResearchOperations@thp.ca).
  3. For studies with an existing agreement please contact the Research Operations Analyst assigned to your file to verify whether revisions are required to your existing agreement. For all other studies, please send an email to [ResearchOperations@thp.ca](mailto:ResearchOperations@thp.ca) to confirm whether this amendment necessitates a research agreement.

1. **PRINCIPAL INVESTIGATOR ATTESTATION**

I have read the information contained in this form. By signing below I agree that:

I have assessed the safety, privacy and ethical implications of this submission and its impact on the study procedures.

I assume full responsibility for the scientific and ethical conduct of this study and agree to conduct this study in compliance with the current edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS), Personal Health Information Protection Act (PHIPA) and any other relevant regulations or guidelines.

I will inform my study team of all changes included in this amendment.

I certify that all researchers and personnel involved in this study at this institution are appropriately qualified and trained to fulfill their role in this study.

I will not implement the change(s) described on this amendment form or deviate from the protocol without final Research Ethics Board approval except to eliminate an immediate risk to study participants.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Principal Investigator |  | Signature |  | Date |