**TRILLIUM HEALTH PARTNERS RESEARCH ETHICS BOARD (REB) ANNUAL RENEWAL APPLICATION**

**REB Study ID#**

| Date form submitted:      Date of initial THP REB approval:       Expiry date of current REB approval:       |  |
| --- | --- |

1. **CONTACT INFORMATION**
2. Person completing this form:

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

1. **STUDY DETALS:**
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. **CURRENT STATUS OF THE STUDY**
2. Study enrollment status: (*this includes prospective enrollment, retrospective and prospective chart reviews where enrollment would be the number of patients whose charts were accessed*).

| [ ]  Open to accrual | [ ]  Closed to accrual | [ ]  On hold |
| --- | --- | --- |
| [ ]  Not started at THP | [ ]  Other (please specify):       |  |

1. Please provide a brief summary of the progress of the study to date:
2. If enrollment is complete, please indicate what study activities are still ongoing (select all that apply):

|  |
| --- |
| [ ]  Participants receiving the study intervention |
| [ ]  Data analysis only (Intervention and follow up complete) |
| [ ]  Post-intervention follow-up of participants |
| [ ]  Data collection (non-intervention studies) |
| [ ]  Preparing publication |
| [ ]  Data/Biological specimen analysis |
| [ ]  Other (please specify):       |

1. Enrollment completion date:       [ ]  **N/A**
2. Please provide an explanation as to why enrollment is currently on hold or has not started:       [ ]  **N/A**
3. **ENROLLMENT**
4. Is your study a:

| [ ]  Retrospective Study (chart review/tissue samples) (compete section b) |
| --- |
| [ ]  Prospective Study (complete section c) |
| [ ]  Both |

1. Retrospective Study (Chart review/Biological specimen samples):

| Number of charts/tissue samples reviewed to date to determine eligibility at THP: |       |
| --- | --- |
| Number of charts/tissue samples included to date in chart review study at THP: |       |

1. Prospective Study:

| Total number of participants expected to be enrolled at all sites: |       |
| --- | --- |
| Total number of participants consent and or screened at all sites to date: |       |
| Number of participants enrolled to date at THP: |       |
| Number of participants who were withdrawn from the study at THP (PI or Self withdrawn): |       |
| Number of participants who withdrew consent at THP: |       |

1. **SERIOUS ADVERSE EVENT REPORTING** **N/A** [ ]
2. Have all Serious Adverse Events (SAEs experienced by THP participants) been reported to the REB? [ ]  Yes [ ]  No [ ]  No SAEs have occurred

*If yes, please attach a copy of the THP summary report of all SAEs that have occurred since the last approval.*

1. Has there been a report from the data safety monitoring committee/board?

[ ]  Yes [ ]  No [ ]  No DSMB

*If yes, have you submitted all your DMSB reports since the past renewal/approval?*

1. **ADDITIONAL INFORMATION**
2. Please confirm that any study amendments proposed in the past year have been submitted for REB approval. If not, please submit proposed amendment(s) on a separate amendment request form:

| [ ]  All amendments have been submitted and approved |
| --- |
| [ ]  No amendments in the past year |
| [ ]  Amendment request form submitted with this renewal form |

1. Please confirm whether there have been any significant protocol deviations/violations or audit findings since last renewal that have not been reported to the REB?

[ ]  Yes [ ]  No

1. If yes, please submit a copy of the Protocol Deviation/Violation Reporting Form with this application.
2. Since the last renewal, has there been any change in the Conflict of Interest information provided to the REB for investigators involved in this study (*Potential Conflicts of Interest can include functioning as an employee or consultant to the study sponsor, direct or indirect financial interest in the drug/device or technology involved in the study or receiving honorarium or other benefits from the sponsor*)?

| [ ]  All potential conflict of interest have been disclosed to the REB |
| --- |
| [ ]  Report attached  |
| [ ]  None since last renewal |

1. Is there any new information in the literature or from other recent studies that would change the rationale or risk/benefit ratio for this study (e.g. changes in standard of care, new information about side effects)? [ ]  Yes [ ]  No
2. If yes, please explain and provide any applicable references:
3. Have there been any participant complaints or feedback from study participants about the study? [ ]  Yes [ ]  No
4. If yes, please describe:
5. **ADDITIONAL COMMENTS/NOTES**

|       |
| --- |

1. **IMPORTANT INFORMATION**

Please ensure that all areas at THP identified as being impacted by the study have been compensated as agreed upon at the onset of the study.

Please also note it is the study team’s responsibility to ensure their renewal request is submitted in a timely manner. Please refer to the Trillium Health Partners Research Ethics Board website for up to date information on submission deadlines and requirements.

If your renewal application is not received by the Research Ethics Office prior to the annual renewal expiry date a suspension of approval may occur. If the REB does not receive your renewal application form within 6 months following your study expiry date, your study will be officially closed and if you wish to continue with the conduct of your study, you will be required to submit a new application for review by the REB.

1. **PRINCIPAL INVESTIGATOR ATTESTATION**

I agree to conduct this study in compliance with the current edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human (TCPS), Personal Health Information Protection Act (PHIPA) and any other relevant regulations or guidelines. I confirm that I have reviewed any adverse events, if applicable, in a timely fashion during the course of the study and these have been reported to the REB. All revisions to the study protocol and consent form have been submitted. I am not aware of any new information that may affect the continuation of the study or require change in the study protocol.

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