**TRILLIUM HEALTH PARTNERS RESEARCH ETHICS BOARD (REB) STUDY CLOSURE/TERMINATION FORM**

| **REB Study ID#** |  Date form submitted:       |
| --- | --- |

1. **STUDY INFORMATION**
2. Full study title:
3. Date of initial THP REB approval:
4. Expiry date of current REB approval:
5. **CONTACT INFORMATION**

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

1. **VERIFICATION OF STUDY CLOSURE**

|  | **Yes** | **No** | **N/A** |
| --- | --- | --- | --- |
| Is recruitment at this site complete? |[ ] [ ] [ ]
| Have all participants completed follow-up? |[ ] [ ] [ ]
| Has all data collection/verification been completed? |[ ] [ ] [ ]
| Are all analyses using identifiable or coded data completed? |[ ] [ ] [ ]
| Have letters of appreciation to participants been sent out? |[ ] [ ] [ ]
| Has the sponsor conducted a close-out visit? |[ ] [ ] [ ]

If you have answered "no" to any of the above questions, the study should remain open. Please complete and submit an annual renewal form or provide an explanation as to why you believe this study should be closed.

Explanation:

1. **STUDY CLOSURE DETAILS**
2. Type of closure:

| [ ]  Study Closure at THP | Closure date at THP       |
| --- | --- |

1. Early termination: [ ]  Yes [ ]  No
2. If yes, study termination at: [ ]  THP [ ]  All sites
3. Please provide reason(s) for early termination of the study:
4. **STUDY STATUS**
5. **Is this study a:**

| [ ]  Retrospective study (chart review/tissue samples) | [ ]  Prospective study | [ ]  Both | [ ]  Other (specify):       |
| --- | --- | --- | --- |

1. **Retrospective study (Chart review/Tissue samples):** [ ]  **N/A**

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

1. **Prospective study:** [ ]  **N/A**

| Number of participants planned for enrollment: |       |
| --- | --- |
| Number of participants that were enrolled: |       |
| Number of participants who completed the study treatment/intervention: |       |
| Number of participants lost to follow-up: |       |
| Number of participants who died before study follow-up completed: |       |
| Number of participants who were withdrawn/ withdrew consent at THP: |       |

1. **ADDITIONAL INFORMATION**
2. Have all Serious Adverse Events (SAEs) that occurred with participants at all study sites been reported to the REB? [ ]  Yes [ ]  No [ ]  No SAEs have occurred
3. If no, please attach a summary statement of all SAEs that have occurred since the last approval.
4. Has this study led to practice changes at THP? [ ]  Yes [ ]  No
5. If yes, please describe:
6. Have any results from the research been published, submitted for publication or presented? [ ]  Yes [ ]  No [ ]  Pending
7. If yes, provide details and attach available publications or abstracts:
8. Please indicate the location and pathway in which your research data will be stored during the retention period:

*\*In the event that you are no longer affiliated with THP, you are responsible to ensure a local research data custodian is identified and THP REB is informed.*

1. **ADDITIONAL COMMENTS/NOTES**

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1. **PRINCIPAL INVESTIGATOR ATTESTATION**

I confirm that:

this study was conducted in accordance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS 2), the Ontario Personal Health Information Protection Act (PHIPA) 2004, and other relevant laws, regulations or guidelines (e.g., Health Canada Part C, Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations, the Medical Devices Regulations, and ICH/GCP Consolidated Guideline E6).

All study-related activities for this research study at THP are now completed and there will be no further collection of data or further contact with participants. Study data will be stored in a secure/confidential manner in accordance with applicable guidelines and regulations.

**I am requesting that the THP REB file on this study for this site be officially closed.**

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