**TRILLIUM HEALTH PARTNERS RESEARCH ETHICS BOARD (REB) CHANGE IN INVESTIGATOR/STUDY PERSONNEL**

| **REB Study ID#**       | Date Form Completed:       |
| --- | --- |

1. **STUDY DETAILS**
2. Full Study Title:
3. Current Principal Investigator:
4. Current Local Principal Investigator:
5. Study Sponsor:

 [ ] Investigator initiated study

1. **NATURE OF CHANGE**

Please complete the section that corresponds with your selection below:

| [ ]  Principal Investigator (Section 3)  | [ ]  Addition of Study Personnel (Section 4)  |
| --- | --- |
| [ ]  Local Principal Investigator (Section 3) | [ ]  Addition of Co-Investigator (Section 4) |
| [ ]  Removal of Co-Investigator (Section 5) | [ ]  Removal of Study Personnel (Section 4) |

1. **CHANGE IN PRINCIPAL/LOCAL INVESTIGATOR** [ ]  **N/A**
2. **Outgoing Investigator**

I will no longer serve on the study noted above. The incoming Investigator has the appropriate knowledge, credentials and training to serve as the Investigator on this study. I have provided him/her with all the necessary documents and critical information about the study. By signing below, I agree to remove myself as the Investigator of the above named study.

| First Name:       | Last Name:       |
| --- | --- |
| Effective Date:       |  |

|  |  |       |
| --- | --- | --- |
| Signature of Outgoing Investigator |  | Date |

1. **Incoming Investigator** [ ]  **N/A**

|  |  |
| --- | --- |
| First Name:       | Last Name:       |
| THP Position/Title:       |  |
| Street Address:       | City:       |
| Province:       | Postal Code:       |
| Phone Number:       | Email:       |

|  |  |  |
| --- | --- | --- |
| Role in the study:  |  |  |
| [ ]  Recruitment [ ]  Data Collection [ ]  Data Analysis[ ]  Screening[ ]  Consent  | [ ]  Data Entry[ ]  Participant Interaction [ ]  Protocol Development [ ]  Manuscript Preparation  | [ ]  Accessing Personal Health Information[ ]  Other (please specify):       |

| *CV attached* [ ]  Yes [ ]  No [ ]  On file  |
| --- |
| TCPS2 Certificate attached [ ]  Yes [ ]  No [ ]  Incomplete [ ]  On file |
| Please confirm that you have obtained all of the required credentials for conducting this research project, including any mandatory trainings [ ]  Yes [ ]  No [ ]  On file Other:       |

1. **Investigator Attestation**:

I attest that the conduct of this study at Trillium Health Partners will be conducted in compliance with the Tri-Council Policy Statement, ICH Good Clinical Practice Consolidation Guidelines; Division 5, Canadian Food and Drug Regulations and the applicable laws and regulations of Ontario;

I attest that the information being collected will be accurate and complete to the best of my knowledge;

I acknowledge that I am responsible for reporting to the Trillium Health Partner Research Ethics Board any proposed modifications or amendments to the protocol, all external (non-local) and internal SAEs, Annual Re-Approvals and updated Investigator Brochures or Product Monographs.

|  |  |       |
| --- | --- | --- |
| Signature of Incoming Investigator |  | Date |

1. **ADDITION/REMOVAL OF STUDY PERSONNEL (including Co-Investigator(s))**
2. Please fill out the table below regarding each additional/outgoing Co-Investigator and/or study personnel:

*(Role, Qualification and Training sections are not applicable for personnel being removed).*

[ ]  **N/A**

| Name (first and Last) | Institutional Affiliation  | Status  | Effective Date | Role in study(see roles below this table) | Associated Qualifications | TCPS2 CORETraining |
| --- | --- | --- | --- | --- | --- | --- |
|       |       | Choose an item. |       |       |       | [ ]  Yes [ ]  No [ ]  Incomplete |
|       |       | Choose an item. |       |       |       | [ ]  Yes [ ]  No [ ]  Incomplete |
|       |       | Choose an item. |       |       |       | [ ]  Yes [ ]  No [ ]  Incomplete |
|       |       | Choose an item. |       |       |       | [ ]  Yes [ ]  No [ ]  Incomplete |
|       |       | Choose an item. |       |       |       | [ ]  Yes [ ]  No [ ]  Incomplete |
|       |       | Choose an item. |       |       |       | [ ]  Yes [ ]  No [ ]  Incomplete |

**Please use corresponding number(s) in ‘Role’ column in the above table**: 1 – Recruitment, 2 - Screening, 3 - Consent, 4 - Data Collection, 5 – Data Entry, 6 - Participant Interaction, 7 - Data Analysis, 8 - Accessing Personal Health Information, 9 – Other (Please specify)

*Please note: All external study personnel must return badges to the security office.*

1. **AFFECTED DOCUMENTS**
2. Please ensure that all documents that are affected by this change are revised and submitted to the REB for review and approval (e.g. consent forms, patient information sheets, etc.).
3. **CONFLICT OF INTEREST** (\*To be completed **only** by new study personnel)

Researchers hold trust relationships with research participants, research sponsors, THP, their professional bodies and society. Researchers, THP and the REB are required to identify and address actual, potential and perceived conflicts of interest ("Conflict of Interest") to maintain public confidence and trust, ensure the integrity of research, discharge professional obligations and ensure accountability.

A Conflict of Interest does not necessarily imply wrongdoing, as a Conflict of Interest depends upon the circumstances, not on the character of the staff members.

A Conflict of Interest does not mean that the research cannot proceed. Many (but not all) Conflicts of Interest can be managed, but always require identification, disclosure to research participants, and if required, other steps to manage Conflicts of Interest. It is up to the REB to determine if the Conflict of Interest can be managed and if the proposed mitigation measures are adequate.

1. Please disclose any/all **[Conflict(s) of Interest](#conflict" \o "When a person or organization has multiple roles / duties / interests / responsibilities that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest, individual or organization)** (COI) **(**[**potentia****l**](#Potiential)**,** **[perceived](#perceived" \o "Where a third party could form the view that other individuals, institutions or seconday interests could improperly influence the primary interest)** and **[actual](#Acutal" \o "Real conflict between a person's primary interest and other institutions, individuals or seconday interest )**) related to this study and how it/they will be managed (e.g., disclosure in consent form, declining role/position with sponsors, additional monitoring strategies such as monitoring the consent process) select all that apply:

 **If no conflict of interest, please check this box:** [ ]  **N/A**

|  | **Areas of Conflict of Interest** | **Type of Conflict of Interest** |
| --- | --- | --- |
| 1. | Choose an item. | Choose an item. |
| 2. | Choose an item. | Choose an item. |
| 3. | Choose an item. | Choose an item. |
| 4. | Choose an item. | Choose an item. |

| 1. Individual(s) involved:
 |
| --- |

| 1. Describe the nature of the Conflict of Interest(s) identified above:
 |
| --- |
| 1. Mitigation strategies (how it/they will be managed, e.g., disclosure in consent form, declining role/position with sponsors, additional monitoring strategies such as monitoring the consent process):
 |

1. **ADDITIONAL CONSIDERATIONS**
2. 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 due to the change in study personnel. For all other studies, please contact ResearchOperations@thp.ca to confirm whether this change necessitates a research agreement.
3. Will participants be notified of this change? [ ]  Yes [ ]  No [ ]  N/A

1. If no, please provide justification:
2. **ATTESTATION:**

I warrant that this study is and will continue to be conducted in accordance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS), the Ontario Personal Health Information Protection Act (PHIPA) 2004, and other relevant laws, regulations or guidelines (e.g., Health Canada, Division 5 of the Food and Drug Regulations, Part 4 of the Natural Health Products Regulations, Medical Devices Regulations, and ICH/GCP Consolidated Guideline E6). I affirm that all research study team members identified above have completed the mandatory training and education in accordance with Trillium Health Partners' institutional requirements.

|  |  |        |
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| Principal Investigator Signature |  | Date |