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

**AMENDMENT DURING PUBLICLY DELCARED EMERGENCY SUBMISSION FORM**

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| This form is to be used for amendments or changes to an approved study plan in order to mitigate or minimize risk to participants, study staff, the public, the organization, or other risks during a publicly declared emergency; such amendments can proceed on notification to the REB **and do not require an REB issued approval letter. Once there is no further risk identified** (e.g. the publicly declared emergency is declared over), study activities **must resume as outlined in the study protocol approved** by the Trillium Heath Partners REB. For amendments which will extend past the publicly declared emergency (i.e. when the publicly declared emergency is declared to be over), a protocol amendment must be submitted to the Trillium Health Partners REB for review and approval after the emergency is declared to be over. |

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| Submission date:       |  |

1. **STUDY DETAILS**

**Study ID#**

1. Full Study Title:
2. Principal Investigator:
3. Please provide a brief summary of the study suitable for a lay audience:

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

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

1. **AMENDMENT DETAILS**
2. Please provide a description of the nature of the change which will be instituted due to a publicly declared emergency:

1. Please provide the justification for the change which will be instituted due to a publicly declared emergency:

1. Please indicate the risk(s) which is being mitigated by the change (select all that apply):

[ ] Risk to Participant(s) [ ] Risk to Researcher

[ ] Risk to Research Personnel [ ] Risk to Public

[ ] Organizational Risk [ ] Other (Please specify):

1. **RESOURCE IMPACT**
2. If the implemented changes to the study activities impact any resources or departments with Trillium Health Partners, you **must first obtain approval from Dr. Rob Reid, SVP Research prior to implementation** of the change. Documentation of approval (e.g. email confirmation) must accompany this submission form.

1. 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 to confirm whether this amendment necessitates a research agreement.
2. **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 Human Subjects (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 confirm the change(s) described on this amendment form which deviate from the protocol are temporary to eliminate an immediate risk (as described above). Once there is no further risk identified (i.e. when the publicly declared emergency is declared over), the research activities will resume as described in the approved protocol.

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