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

**SAFE RESEARCH PRACTICES FORM**

The THP REB is committed to supporting safe research at Trillium Health Partners during the pandemic. This form is designed to delineate any risks and benefits of proposed research activities in light of the recent pandemic, and the safety measures required to safely engage in research going forward.

One copy of this form is required to accompany **new study** submissions, submissions relating to **restarting an already approved research study** and **amendment submissions** (excluding minor amendments) until further notice. For information on this form or requirements, please contact the Research Ethics Board Office at THPREB@thp.ca.

1. **STUDY INFORMATION:**

|  |  |
| --- | --- |
| **Study Title** |       |
| **Principal Investigator** |       |
| **REB ID# (if applicable)** |       |
| **Study Site(s):** | [ ]  Credit Valley Hospital [ ]  Mississauga Hospital [ ] Queensway [ ]  Other:       |

1. **SUBMISSION INFORMATION:**

|  |  |
| --- | --- |
| Nature of Submission:  | [ ]  New study submission [ ]  Amendment to previously approved study[ ]  Restarting research under exception request |
| Planned (re)start date:  |       |

1. **IN-PERSON RESEARCH VISITS/CONTACT:** [ ] Not Applicable *(skip this section)*

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| --- | --- |
| How will the study team adhere to provincial and THP guidelines for safe in-person contact: | [ ]  Use of PPE [ ]  Physical Distancing ≥ 2meters (whenever possible) [ ]  Sanitization of all materials, equipment, and area[ ]  Adequate space & resources to accommodate research visits and distancing requirements[ ]  Other (explain):       |
| How will PPE be secured for study purposes: | [ ]  Sponsor supplied [ ]  Purchased using research funding [ ]  Visits planned concurrently with clinical care and no additional PPE required[ ]  Other (explain):       |
| Does participation in the study increase the chance of community exposure and/or spread of COVID-19? | [ ]  No [ ]  Yes (provide justification):       |
| Will participation in the study increase the risks to third parties/society by increasing risk of COVID-19 exposure? | [ ]  No [ ]  Yes (provide justification):       |
| Please state the rationale for in-person research being conducted now, during the COVID-19 pandemic, rather than later? For example, is it considered beneficial to participants and/or is it urgent that the research be conducted as soon as possible due to research or researcher factors such as grants or educational requirements? 2 |       |
| Please discuss any anticipated risks/benefits of specifically related to conducting research through in-person visits at this time (e.g. increased risk of exposure to COVID-19 balanced by the potential for direct health benefit by in person treatment, etc.)2: |       |

1. **VIRTUAL RESEARCH VISITS:** [ ] Not Applicable *(skip this section)*

|  |  |
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| Which virtual platform(s) will be used to facilitate virtual research visits: | [ ]  Skype [ ] Zoom [ ] WebEx[ ]  Other:       |
| What measures are in place to maximize safety when engaging virtually? | [ ]  Suggest personal/identifiable items are removed from view[ ]  Participant to confirm they have a confidential space[ ]  Safety plan for participants requiring urgent follow up[ ]  Offer alternative secure method (e.g. phone)[ ]  Other (explain):        |
| Do virtual visits exclude any populations based on socio-economic status or raise other ethical issues related to fairness and equity? | [ ]  No [ ]  Yes (provide justification):       |
| Please discuss any anticipated risks/benefits specifically related to conducting research in virtual interactions during the COVID-19 pandemic (e.g. changes to privacy, confidentiality, ability of research team to respond to participants requiring urgent follow up, balanced by the ability to engage in the research which may have societal benefit, etc.)2: |       |

1. **COVID-19 SPECIFIC CONTENT**  [ ] Not Applicable *(skip this section)*

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| Is the COVID-related content necessary to complete the research project, e.g. can this research be done without it?1 |       |
| Please describe the anticipated benefits of including COVID-19 related content to the current study (to research participants, to society or specific communities)1: |       |

1. **ADDITIONAL COMMENTS/NOTES**

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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 Human Subjects (TCPS), Personal Health Information Protection Act (PHIPA) and any other relevant regulations or guidelines.

I will inform my study team of all required or updated procedures as outlined above.

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.

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