

Research Ethics Board (REB)

**RESEARCH IMPACT FORM**

**INSTRUCTIONS**

* This form is required for **initial** REB review of new research projects that involve contact with or observation of human study participants. This form is not required for retrospective chart reviews.
* Completed Departmental Impact Forms must be provided as part of the applicant’s REB submission to the RVH REB. If the proposed research utilizes a Clinical Trials Ontario Qualified REB as the REB of Record, please submit the completed impact form to research@rvh.on.ca.
* No research shall be initiated at RVH until full ethics approval has been obtained from the RVH REB or other qualified REB of Record

**PROCESS**

1. The Principal Investigator (PI) is responsible for obtaining the approval(s) of the Medical and Operational Directors from each impacted department prior to submitting the application to the RVH REB. For assistance identifying specific individuals, please contact the RVH Research Institute at research@rvh.on.ca.
2. The PI should complete each applicable section listed below. A brief summary of how the study impacts each department should be provided. The Study Protocol and proposed Budget must be presented with this form when obtaining approval from departmental representatives.
3. Departmental representatives are responsible for reviewing and understanding this form, the Study Protocol, and proposed Budget to a level they consider appropriate. By signing this form, departmental representatives agree to allow the study to be conducted in their department.
4. The Principal Investigator should be amenable to any reasonable study modifications proposed by the departmental representative. Questions or concerns should be addressed to the Principal Investigator and/or Primary Contact indicated below.

**SECTION A: STUDY INFORMATION**

**REB STUDY NUMBER: (Internal Use Only) only)**

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| Full Study Title: Click here.  |
| Abbreviated Study Title (max. 10 words): Click here. | Study Sponsor:Click here.  | Protocol # Click here. |
| Principal Investigator Name: Click here.  | [ ]  Clinical Trial [ ]  Observational Trial[ ]  Chart Review [ ]  Other: Click here. |
| REB Board of Record: Click here.  | Anticipated Start Date: Click to enter a date. |
| Anticipated Local Enrollment: Click here.  | Anticipated End Date: Click to enter a date. |
| Name of Primary Contact: Click here.  | Primary contact email/phone: Click here.  |

**SECTION B: PRINCIPAL INVESTIGATOR STATEMENT**

[ ]  I have reviewed the form and determined that this study involves the use of hospital resources, and/or patient care areas, and/or staff. I have, to the best of my knowledge, indicated the areas where departmental approval is necessary and have obtained the appropriate signatures as indicated on the form. I confirm that no research shall be initiated at RVH until full ethics approval has been obtained from the RVH REB or other qualified REB of Record

OR

[ ]  I have reviewed the form and attest that this study does not involve any hospital resources, patient care areas, or staff, and that no departmental approvals are required for the conduct of this study

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

**SECTION C: IMPACT SUMMARY AND DEPARTMENT APPROVALS**

The Principal Investigator (PI) is responsible for obtaining approval(s) from the Medical and Operational Director of each impacted department prior to submitting the application to the RVH REB. Note: If the study requires an agreement, a draft of the research contract must be submitted to the RVH Research Office (research@rvh.on.ca) for review and execution prior to initiating the research.

By signing below, departmental representatives attest to:

* Having read and understood the study protocol and proposed budget
* Having understood the clinical and financial impact of the research study on their department
* Support the research study within their respective departments, in accordance with the requirements set out in the study protocol and clinical trial agreement
* Act as the overarching study delegate for their respective department, who will communicate any study or research specific requirements that are above standard of care practices to all staff within their department

[ ]  **Biomedical Engineering (BIOMED) Impact Summary:**

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| [ ]  Standard of Care [ ]  Above Standard of CareClick or tap here to enter text. |
| Authorized departmental representative(s): |
| Full NameClick here. | RoleOperations Director | Signature | Date |

[ ]  **Cancer Program Impact Summary:**

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| --- |
| [ ]  Standard of Care [ ]  Above Standard of CareClick or tap here to enter text. |
| Authorized departmental representative(s): |
| Full NameClick here. | RoleOperations Director | Signature | Date |
| Click here. | Medical Director |  |  |

[ ]  **Cardiovascular Program Impact Summary:**

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| [ ]  Standard of Care [ ]  Above Standard of CareClick or tap here to enter text. |
| Authorized departmental representative(s): |
| Full NameClick here. | RoleOperations Director | Signature | Date |
| Click here. | Medical Director |  |  |

[ ]  **Emergency Impact Summary:**

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| [ ]  Standard of Care [ ]  Above Standard of CareClick or tap here to enter text. |
| Authorized departmental representative(s): |
| Full NameClick here. | RoleOperations Director | Signature | Date |
| Click here. | Medical Director |  |  |

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| [ ]  Standard of Care [ ]  Above Standard of CareClick or tap here to enter text. |
| Authorized departmental representative(s): |
| Full NameClick here. | RoleChief Performance Officer | Signature | Date |

[ ]  **Health Information Management Impact Summary:**

[ ]  **Imaging Services Impact Summary:**

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| [ ]  Standard of Care [ ]  Above Standard of CareClick or tap here to enter text. |
| Authorized departmental representative(s): |
| Full NameClick here. | RoleOperations Director | Signature | Date |
| Click here. | Medical Director |  |  |

[ ]  **Intensive Care Impact Summary:**

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| [ ]  Standard of Care [ ]  Above Standard of CareClick or tap here to enter text. |
| Authorized departmental representative(s): |
| Full NameClick here. | RoleOperations Director | Signature | Date |
| Click here. | Medical Director |  |  |

[ ]  **Laboratory Services Impact Summary:**

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| [ ]  Standard of Care [ ]  Above Standard of CareClick or tap here to enter text. |
| Authorized departmental representative(s): |
| Full NameClick here. | RoleOperations Director | Signature | Date |
| Click here. | Medical Director |  |  |

[ ]  **Maternal, Newborn, Child & Youth Program Impact Summary:**

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| [ ]  Standard of Care [ ]  Above Standard of CareClick or tap here to enter text. |
| Authorized departmental representative(s): |
| Full NameClick here. | RoleOperations Director | Signature | Date |
| Click here. | Medical Director |  |  |

[ ]  **Medicine Program Impact Summary:**

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| [ ]  Standard of Care [ ]  Above Standard of CareClick or tap here to enter text. |
| Authorized departmental representative(s): |
| Full NameClick here. | RoleOperations Director | Signature | Date |
| Click here. | Medical Director |  |  |

[ ]  **Mental Health & Addictions Impact Summary:**

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| [ ]  Standard of Care [ ]  Above Standard of CareClick or tap here to enter text. |
| Authorized departmental representative(s): |
| Full NameClick here. | RoleOperations Director | Signature | Date |
| Click here. | Medical Director |  |  |

[ ]  **Pharmacy Impact Summary:**

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| [ ]  Standard of Care [ ]  Above Standard of CareClick or tap here to enter text. |
| Authorized departmental representative(s): |
| Full NameClick here. | RoleOperations Director | Signature | Date |

[ ]  **Professional Practice, Infection Prevention and Control, and Allied Health Impact Summary:**

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| [ ]  Standard of Care [ ]  Above Standard of CareClick or tap here to enter text. |
| Authorized departmental representative(s): |
| Full NameClick here. | RoleOperations Director | Signature | Date |

[ ]  **Renal Program Impact Summary:**

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| [ ]  Standard of Care [ ]  Above Standard of CareClick or tap here to enter text. |
| Authorized departmental representative(s): |
| Full NameClick here. | RoleOperations Director | Signature | Date |
| Click here. | Medical Director |  |  |

[ ]  **Surgical Services Program Impact Summary:**

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| [ ]  Standard of Care [ ]  Above Standard of CareClick or tap here to enter text. |
| Authorized departmental representative(s): |
| Full NameClick here. | RoleOperations Director | Signature | Date |
| Click here. | Medical Director |  |  |

[ ]  **Other (please specify; add additional sections as needed):** Click or tap here to enter text.

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| [ ]  Standard of Care [ ]  Above Standard of CareClick or tap here to enter text. |
| Authorized departmental representative(s): |
| Full NameClick here. | RoleOperations Director | Signature | Date |
| Click here. | Medical Director |  |  |