

Research Ethics Board (REB)

**RESEARCH IMPACT FORM**

**INSTRUCTIONS**

* The Research Impact Form is required for **initial** REB review of new research projects that involve contact with and/or observation of human study participants. This form is **not** required for chart reviews
* Completed Research Impact Forms must be provided as part of the applicant’s REB submission to the RVH REB. If multiple departments are impacted, please complete a Research Impact Form for each impacted department
* If the proposed research utilizes a Clinical Trials Ontario (CTO) qualified REB as the REB of Record, please submit the completed form to [research@rvh.on.ca](mailto:research@rvh.on.ca) before submitting your Centre Initial Application in CTO Stream
* If the RVH REB is acting as the board of record and the proposed research is being conducted at an organization external to RVH, please follow the external organization’s operational approval requirements
* No research shall be initiated at RVH until full ethics approval has been obtained from the RVH REB or other RVH-recognized REB of Record

**PROCESS**

1. The Principal Investigator (PI) is responsible for identifying and obtaining approval from authorized representatives of **each** impacted department **prior** to submitting the application to the RVH REB. For assistance identifying specific authorized representatives, please contact the RVH Research Institute at [research@rvh.on.ca](mailto:research@rvh.on.ca)
2. The PI should complete each applicable section listed below. The study protocol and applicable supporting documentation should be provided to departmental representatives with this form
3. Departmental representatives are responsible for reviewing and understanding this form, the study protocol, and applicable supporting documentation to a level they consider appropriate 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. | Experimental Study  Observational Study  Other (specify): Click here. |
| Principal Investigator Name: Click here. | Principal Investigator Email: Click here. |
| Study Coordinator Name: Click here.  Not applicable | Study Coordinator Email: Click here.  Not applicable |
| Anticipated Study Start Date: Click to enter a date. | Anticipated Study End Date: Click to enter a date. |
| Anticipated Local Enrollment: Click here. | REB of Record: Click here. |
| Study Sponsor: Click here.  Not applicable | Study Protocol #: Click here. |

**SECTION B: DEPARTMENTAL APPROVALS**

By signing below, the departmental representative confirms that they will:

* Support the research study within their department in accordance with the requirements set out in the study protocol; and
* Act as the overarching study delegate for their respective department and communicate any study or research specific requirements that are above standard of care practices to applicable staff within their department

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| **Department:**  Click here. | | | | | | |
| Financial Impact on Department:  Revenue Gain  Revenue Neutral  Revenue Loss | | | | | | |
| Briefly describe the department’s role in the study (max. 100 words): Click here. | | | | | | |
| Department Test/Procedure/Hardware  (add more below as needed) | | Standard of Care | Not Standard of Care | | Additional Comments | |
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| Authorized departmental representative(s): | | | | | | |
| Full Name  Click here. | Role  Operations Director | | | Signature | | Date |
| Click here. | Medical Director  Not applicable | | |  | |  |