

RVH Research Ethics Board (REB)

**ANNUAL RENEWAL FORM**

**INSTRUCTIONS**

* The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2018) and the principles of Good Clinical Practices, as described by the International Conference on Harmonization, require REB review of ongoing studies; this is achieved by the completion of this Annual Renewal Form
* This form may be used to renew RVH REB approval for any active studies for one (1) year.
* **All sections** of this form **MUST** be completed before it will be considered for REB review. Incomplete submissions will be returned to the Principal Investigator and/or Study Coordinator for completion

**SUBMISSION PROCEDURE**

* Please submit three (3) paper copies and one (1) scanned or electronic copy of your completed application to the address below. Do not staple any sections of your submission; use paperclips to keep copies together

RVH Research Ethics Board

Centre for Education & Research, Room 3357

Royal Victoria Regional Health Centre

201 Georgian Drive, Barrie, ON

L4M 6M2

Email: ethics@rvh.on.ca

Phone: 705-728-9090 Ext. 43318

* To ensure timely renewal of your study and to avoid suspension of approval, please submit this form to the RVH REB at least thirty (30) days prior to the study expiration date.

**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. |
| RVH REB Study #: Click here.  | 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: Click here.  |

**SECTION B: GENERAL STUDY INFORMATION**

1. Date of initial RVH REB approval: Click or tap to enter a date.
2. Please complete the following sections, as applicable:

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| If study was initially submitted using the **Application for Medical Chart Review**: |
| How many medical charts were planned for review at RVH? | Click here to enter text. |
| How many medical charts were actually reviewed at RVH? | Click here to enter text. |

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| If study was initially submitted using the **General Research Application**: |
| Is this study open for enrollment at RVH?If “No”, please explain: Click here to enter text. | [ ]  Yes [ ]  No |
|  |
| **How many study participants at RVH:** |
| Were planned for enrollment? | Click here to enter text. |
| Have been consented? | Click here to enter text. |
| Have been enrolled? | Click here to enter text. |
| Are currently receiving study treatment/intervention? | Click here to enter text. |
| Have completed study treatment/intervention and follow-up? | Click here to enter text. |
| Have withdrawn consent? | Click here to enter text. |
| Have there been any changes to the informed consent form(s) that the RVH REB has not been previously notified of? If “Yes”, please submit an Amendments, Notifications, and Ongoing Communication Form and other relevant documentation with this submission | [ ]  Yes [ ]  No |
| Have all reportable events (e.g., Serious Adverse Events (SAEs), protocol deviations) been reported to the RVH REB?If “No”, please explain: Click here to enter text. | [ ]  Yes [ ]  No |
| In the opinion of the Principal Investigator, is there a concern or trend in any SAEs that have occurred with study participants at RVH?If “Yes”, please provide details and action(s) taken: Click here to enter text. | [ ]  Yes [ ]  No[ ]  No SAEs occurred |

1. Has there been a lapse in REB approval for this study? [ ]  Yes [ ]  No

If “Yes”, please provide the reason for the lapse and identify steps taken to prevent future lapses (max. 200 words):

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| Click here to enter text.  |

1. Since the last RVH REB renewal, is there any change in any ethical or scientific information outside of the study protocol that would be relevant to the continuing review of this study? [ ]  Yes [ ]  No

If “Yes”, please explain:

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| Click here to enter text.  |

1. Since the last RVH REB renewal, has there been any change in the Conflicts of Interest information provided in the initial (original) RVH REB application?

If “Yes”, please explain (max. 200 words):

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| Click here to enter text.  |

1. Have any results from this research been published, submitted for publication, or presented? [ ]  Yes [ ]  No

If “Yes”, please provide details and attach available publications or abstracts (max. 200 words):

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| --- |
| Click here to enter text.  |

1. If desired, please provide any additional information relevant to the renewal of this study:

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| --- |
| Click here to enter text.  |

1. Person completing this form:

|  |  |  |
| --- | --- | --- |
| First: Click here. | Last: Click here. | Degree(s): Click here. |
| Institution: Click here. | Program: Click here. | Department: Click here. |
| Street Address: Click here. | Room/Suite #: Click here. | City: Click here. |
| Province: Click here. | Postal Code: Click here. | Email: Click here. |
| Telephone: Click here. | Fax: Click here. | RVH Affiliated? [ ]  Yes [ ]  No |

**SECTION C: PRINCIPAL INVESTIGATOR STATEMENT & SIGNATURE**

* I confirm that the above information is accurate
* I assume full responsibility of for the scientific and ethical conduct of this study and agree to conduct this study in compliance with Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2018), The Ontario Personal Health Information Protection Act, 2004, S.O. 2004, c. 3, Sched. A, and any other relevant guidelines and regulations
* I certify that all study team members in this study at RVH are appropriately qualified and trained to fulfill their role in this study

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