

RVH Research Ethics Board (REB)

**STUDY CLOSURE 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 a final report for the closure/termination of research studies. This is achieved by the completion of this Study Closure Form
* This form may be used to close, terminate, or withdraw a study from further RVH REB review. This form should be submitted when there is no further participant involvement and all data collection, clarification, and transfer is complete (including all access to the study participant’s medical record). Submission of this form indicates that these activities have ceased, the study does not require continuing ethics approval, and that the RVH REB study file can be closed
* **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

**SECTION A: STUDY INFORMATION**

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

|  |
| --- |
| 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 study completed or terminated at RVH: Click or tap to enter a date.
2. Was this study completed or terminated prematurely or never opened for enrollment (select each that apply)?

[ ]  Yes, this study was never opened for enrollment

[ ]  Yes, this study was terminated prematurely

[ ]  No

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

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

1. Please complete the following sections, as applicable:

|  |
| --- |
| 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. |

|  |
| --- |
| If study was initially submitted using the **General Research Application**: |
| **How many study participants at RVH:** |
| Were planned for enrollment? | Click here to enter text. |
| Were consented? | Click here to enter text. |
| Were enrolled? | Click here to enter text. |
| Completed the study intervention and follow-up? | Click here to enter text. |
| Withdrew 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 any change in the Conflicts of Interest information provided in the initial (original) RVH REB application?

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

|  |
| --- |
| 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):

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

If “No”, describe the plans for dissemination of the results or provide justification for why the results will not be disseminated (max. 200 words):

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

1. Will study participants be given the results of the study? [ ]  Yes [ ]  No

If “No”, please provide reasoning (max. 200 words):

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

1. If desired, please provide any additional information relevant to the closure 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 there is no further participant involvement and all data collection, clarification, and transfer is complete (including access to the study participant’s medical record)
* I certify that the study data will be retained and disseminated according to applicable guidelines and regulations
* I request that the RVH REB study file be closed

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