



RESEARCH ETHICS BOARD
End of Study
 Typed Original Signed Hardcopies **ONLY**

DO NOT STAMP OR AMEND THE REB SUBMISSION FORM

DO NOT SEND BY FAX OR EMAIL

This form is to be used only if all data have been collected, contact with participants has concluded, the site has been closed and the study is ready for archiving.

| | |
|------------------|-----------------|
| Submission Date: | HRH REB Number: |
|------------------|-----------------|

| | |
|---|---------------------------|
| PRINCIPAL INVESTIGATOR: | |
| STUDY TITLE: | |
| SPONSOR NAME: | |
| PROTOCOL NUMBER: | PROGRAM: |
| DATE OF STUDY START-UP (ACTIVATION DATE): | DATE CLOSED TO ENROLMENT: |
| REB EXPIRY DATE: | |

Has the study been closed prematurely? YES NO

If YES what actions were taken to inform research participants (both completed and ongoing participants) to ensure their optimal treatment.

Reason for Study Closure:
 Termination Date: _____

STUDY STATISTICS FOR ENTIRE STUDY PERIOD (For HRH ONLY)

| | |
|--|-------|
| Number of Participants Enrolled | _____ |
| Number of Participants that have Completed Intervention and Follow-Up | _____ |
| Number of Participants that have had a Serious Adverse Event | _____ |
| Number of Participants that have dropped out or have been withdrawn from the Study | _____ |
| Number of protocol violations | _____ |
| Number of Participants included in Retrospective Review (Chart Reviews Only) | _____ |

Have all Local Serious Adverse Events been reported to the REB? YES NO

| | |
|----------------------------|----------------------------|
| REB Date of Receipt | Database Entry Date |
| | |

****If NO then submit unreported SAE on appropriate HRH Submission Form and submit to the REB along with End of Study Submission Form***

DATA COLLECTION

Has all the Data been collected for the study?

**If answer is NO see below*

YES NO

Has all contact with Study Participants concluded?

**If answer is NO see below*

YES NO

Has all Study-related data analysis been complete?

**If answer is NO see below*

YES NO

****If answer is NO to any of the above questions, the Study CAN NOT be closed out and will require an HRH REB Annual/Interval Review Submission until all questions can be answered YES and the study has concluded.***

Please attach a copy of the final report/abstract(s) available to date

Attached

Please provide a brief summary of the study:

FOR INDUSTRY SPONSORED STUDIES ONLY

Provide the date the site close out visit with the Study Sponsor occurred.

PRINCIPAL INVESTIGATOR'S SIGNATURE

I confirm that this study is now complete and the Research Ethics Board study file is to be closed and archived.

Print

Name of Principal Investigator

Signature of

Principal Investigator

Date

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**SEND TYPED SIGNED ORIGINAL TO THE OFFICE OF RESEARCH ETHICS,
HUMBER RIVER HOSPITAL, 200 CHURCH STREET, ROOM CB-21,
WESTON, ONTARIO M9N 1N8
Phone: 416-243-4562**