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**RESEARCH ETHICS BOARD – STUDY CLOSURE/TERMINATION REPORT**

**INFORMATION & INSTRUCTION SHEET**

**WHEN SHOULD A STUDY CLOSURE/TERMINATION REPORT BE SUBMITTED?**

According to the joint Network of Networks and CAREB Standard Operating Procedure (SOP 406.001), which has been adopted by the Royal Ottawa Health Care Group REB, study closure/termination reports should be submitted when:

* There is no further participant involvement at the site
* There will be no new data collected from the study participants
* Databases are “locked” and queries have been resolved
* Sponsor closeout activities have been completed (if applicable)

**Note:** When conducting studies that are multi-center in nature, the study should not be terminated with the REB until all sites have completed recruitment/study activities. New information may arise or there may be requirements to collect additional information in which case the study must remain “open.” Annual renewals (progress reports) should be submitted until all sites are “complete.”

Submitting this form tells the REB that this study is now complete.

**WHAT HAPPENS AFTER MY STUDY IS TERMINATED?**

* Once a study is “closed” the REB will not accept further submissions related to the study. It will, however, accept and acknowledge study related documents as applicable.
* If a sponsor requests additional information once a study is closed, an application must be submitted to the REB for approval before the information may be accessed/obtained for the sponsor.

**WHAT ARE MY RESPONSIBILITIES AS AN INVESTIGATOR?**

Investigators are responsible for informing the REB that a study is complete. A summary of the study’s outcome and recruitment status must be included. Where applicable, the investigator must provide the regulatory authorities with any required reports.

For studies that are registered on [www.clinicaltrials.gov](http://www.clinicaltrials.gov), registration information must be updated and results must be posted as soon as possible.

For studies that are regulated by Health Canada, it is the investigator’s responsibility to retain the study documents/records for a period of 15 years.

For those studies that are not regulated, records must be stored for 10 years.

**A Post-Study Report must be submitted to the REB with their Study Closure Form (except for Chart Reviews).**

*Please delete this page once you have completed the form. Do not submit this page with the form.*

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**RESEARCH ETHICS BOARD – STUDY CLOSURE/TERMINATION REPORT**

Study Closure/Termination Reports should only be submitted to the REB when the study is deemed complete and all data has been collected. No further reviews will be required and all study activities have ceased.

|  |  |
| --- | --- |
| **REB NUMBER:** Click here to enter text.  **PRINCIPAL INVESTIGATOR:** Click here to enter text.  **PROTOCOL TITLE:** Click here to enter text. | **DATE:** Click here to enter a date.  **LAST DATE OF APPROVAL:** Click here to enter a date.  **DATE OF STUDY CLOSURE:** Click here to enter a date. |

|  |  |
| --- | --- |
| **Study Type:** | Clinical Trial (Drug or Device or NHP) ***Regulated***  Clinical Trial (Drug or Device or NHP) ***Not Regulated*** |
|  | Clinical Trial (other interventional) |
|  | Surveys/Interviews |
|  | Observational  Chart Review |

**Study Termination Report Summary**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Information Required** | | **Royal Clients** | **Total Family Members of Royal Clients** | **Community** | **Online Anonymous** | **Other** |
| 1. | **Enrollment Target –** The total number of participants expected to be enrolled at this site, as indicated in the protocol and approved by the REB during the initial approval OR following a sample size amendment approval. |  |  |  |  |  |
| 2. | **Total Enrollment –** The total number of participants who have consented to participate ***since the study opened to recruitment***. |  |  |  |  |  |
| 3. | **Total Enrollment Since Last Approval –** This is the total number of participants that have been enrolled ***since the date of the last REB approval***. |  |  |  |  |  |
| 4. | **Total Withdrawals to Date –** The total number of participants who have ***withdrawn since the start of the study***. |  |  |  |  |  |
| 5. | **Total Withdrawals Since Last Approval –** The Total number of participants who have ***withdrawn from the study since the last REB approval***. |  |  |  |  |  |
| 5. | **Reason for Withdrawals –** List the reasons participants have withdrawn from the study (e.g. 2 patients moved, 1 patient died, 3 non-compliant with study) |  |  |  |  |  |
| 6. | **Total Participants Screened –** Provide the total number of participants screened for this study (this includes those identified as screen failures). |  |  |  |  |  |

**Did you recruit participants from The Royal Research Registry?** ☐ Yes ☐ No

**PRESENTATIONS & PUBLICATIONS ASSOCIATED WITH THIS STUDY**

*Please provide a brief description or list of all presentations & publications to date:*

Click here to enter text.

**SUMMARY OF RESEARCH ACTIVITY SINCE LAST APPROVAL**

*Please provide a* ***brief*** *description of the overall study activity that has occurred. This may include information about recruitment challenges, DSMB review, adverse events, interim and final analyses, and results.*

Click here to enter text.

**Is a Post-Study Report included in this submission?** ☐ Yes ☐ No, this study is a Chart Review

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*I confirm to the best of my knowledge that the information provided above is accurate and true.*

The records for this study will be retained for a period of 10 years (non-regulated research)

This trial was regulated by Health Canada therefore the records will be retained for a period of 15 years

*This study has been conducted in compliance with TCPS2, ICH Good Clinical Practice Guidelines (ICH-GCP) and all applicable regulations and institutional policies and procedures.*

*All study activities are complete and the study may be terminated with the REB.*

**Qualified/Principal Investigator Name (typed):** Click here to enter text.

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**Qualified/Principal Investigator Signature** **Date of Signature:** Click here to enter a date.

***You must keep a copy of this completed form for your study file***