GUIDANCE NOTES FOR STUDY CLOSURE

INTRODUCTION

These guidance notes are intended to ensure the applicant has the necessary information to complete the Study Close-out Request form on the ROMEO Research Platform.

GUIDANCE NOTE #1: WHEN SHOULD I CLOSE MY STUDY WITH THE FHREB?

A study close-out application should be submitted only when all study related procedures related to the human participants are complete. This includes all data collection, whether directly from the participant via surveys and interviews, or from secondary sources such as medical charts.

A study that has completed all data collection, and is now in the data analysis stage may be closed. However, if there is a possibility of contacting participants or accessing medical records in order to verify/correct data during the analysis stage, the study should NOT be closed.

Studies that involve analysis of tissue should only be closed when no more tissue samples are being acquired (e.g., withdrawn from tissue banks or other research groups).

Industry-sponsored clinical trials should only be closed AFTER the site close-out visit, regardless of whether all study procedures are complete.

GUIDANCE NOTE #2: HOW DO I CLOSE MY STUDY WITH THE FHREB?

Please complete the Study Close-out Request form on the ROMEO Research Platform. This form collects information on total enrollment/records accessed, storage of research-related documents, and overall implementation of the study. Please ensure all sections are complete.

Once the application is reviewed by the FHREB, an Acknowledgement of Study Closure will be sent to the Principal Investigator and Main Contact through the ROMEO Research Platform.

GUIDANCE NOTE #3: REQUIRED INFORMATION

The principal investigator is required to provide the following information in the study close-out application:

- the Principal Investigator's affirmation that all data collection and study procedures involving human participants is completed;
- total number of research participants enrolled at the Fraser Health site(s), including the number of withdrawals; and,
- the final disposition /storage of all research-related study document, including electronic data; and

For clinical trials, the Principal Investigator must also provide the following information:

- the number of related or possibly related serious and unexpected adverse events, if applicable;
- the date of the study monitor's final close-out visit, for industry sponsored research; and,
- any other information required by the study sponsor.

GUIDANCE NOTE #4: AFTER THE STUDY IS CLOSED

The Principal Investigator is responsible for the storage of the research-related documents. For Health Canada regulated studies, Principal Investigators are required to archive the study-related documents for 15 years. For all other study, the FHREB expects the Principal Investigator to maintain the research-related documents for five years. Exceptions to this requirement should be detailed in the Study Close-Out Request.

GUIDANCE NOTE #5: WHAT IF I DO NOT CLOSE THE STUDY?

The FHREB Office will send a reminder to the Principal Investigator and Main Contact four weeks prior to the ethics expiry date to either renew or close the study. If no response is received by the expiry date, the FHREB will close the ethics file and issue a notification of study closure. All study-related procedures must cease upon receipt of this notification. If the Principal Investigator wishes to reopen the study, a new application must be submitted to the FHREB for review and approval.