Fraser Health Research Ethics Board
Department of Evaluation and Research Services , FHA
#400, 13450 102 Avenue, Surrey, BC V3T 0H1
Phone: 604.587.4436 Fax: 604.930.5425

GUIDANCE NOTES FOR APPLICATION FOR RENEWAL OF A PREVIOUSLY APPROVED STUDY

INTRODUCTION

These guidance notes are intended to ensure the applicant has the necessary information to complete the Renewal request section of the Integrated Post-Approval Application Form.

GUIDANCE NOTE #1: WHEN DO I NEED TO SUBMIT A RENEWAL APPLICATION?

For studies with ongoing research procedures with participants and/or data collection, the Principal Investigators must submit a renewal application PRIOR to the approval expiry date listed on the most recent Certificate of Ethical Approval. The expiry date is usually (and never more) than one year from the initial approval/most recent renewal date.

Studies in which all research procedures with participants and data collection is complete with the exception of data analysis may be closed at the time of expiry. However, if there is a possibility of contacting the participants and/or accessing secondary data for the purposes of data verification during the analysis stage, the study must be renewed.

Studies subject to full board review must submit their renewal applications at minimum two weeks prior to the full board meeting preceding their expiry date to ensure the renewal application is reviewed and approved prior to the study expiry.

The FHREB Office will issue an email reminder to the Principal Investigator and Main Contact four weeks prior to the expiry date. However, it is the responsibility of the Principal Investigator to ensure the study is renewed on time.

GUIDANCE NOTE #2: HOW TO SUBMIT A RENEWAL APPLICATION

The Principal Investigator and/or designate must complete Section B of the Post-Approval Research Ethics Form and submit the form and required supporting documentation by email to REB@Fraserhealth.ca.

GUIDANCE NOTE #3: RENEWAL SUBMISSION REQUIREMENTS

The renewal submission must be **signed by the Principal Investigator and/or designate**. If the main contact for the study has changed, this must be specified on the first page of the application form to ensure the renewal certificate is released to the appropriate contact.

Current enrolment numbers must be provided with the renewal application. For chart reviews and other studies not directly enrolling human participants, the number records and secondary sources accessed for the study should be submitted.

3.1 Studies with direct human participant recruitment

Studies with direct human participant recruitment must submit a copy of the currently approved consent form with the renewal application if they are continuing to recruit participants. If enrolment for the study is closed, the consent form is not required.

3.2 Above-minimal risk studies

For above-minimal risk study renewals, the TCPS 2 Core Tutorial Certificate from the Principal Investigator must be submitted with the first renewal.

GUIDANCE NOTE #4: SUBMISSION CRITERIA FOR FULL BOARD OR DELEGATED APPROVAL

It is the responsibility of the Principal Investigator to indicate whether Full Board Review is required. Studies sponsored by the United States Department of Health and Human Services (DHHS) (i.e., NIH and its related institutes including NCI, U.S. Centre for Disease Control) may require Full Board Review under 45 CFR 46.109 (e) and/or 46 CFR 110 (Code of Federal Regulations). Studies that are funded by other American federal agencies (e.g. United States Department of Defense) may require Full Board Review under 21 CFR 56.110. Most other studies will qualify for delegated review.

The FHREB reserves the right to refer any renewal submission to full board review for any reason.

GUIDANCE NOTE #5: SUMMARY OF STUDY PROGRESS

The summary of progress to date should include information on whether participants are still participating in the research study, especially, when in the case of clinical trials, the trial is closed to enrolment. Information about the ability to recruit participants is also appropriate as is any information about the results from any interim analyses.

GUIDANCE NOTE #6: SUMMARY OF SERIOUS AND UNEXPECTED ADVERSE EVENTS

The Principal Investigator is responsible for summarizing the impact of any Serious AND Unexpected adverse events either observed throughout the study period or submitted to the Principal Investigator by the sponsor for other sites in multi-centre trials.

GUIDANCE NOTE #7: SUMMARY OF NEW INFORMATION

This section should describe any changes not included in other sections that may impact the ethical basis or risk of the research design, e.g., changes in conflict of interest, interim findings, changes in Health Canada approval of the study drug, etc.

GUIDANCE NOTE #8: WHAT HAPPENS IF I DO NOT RENEW BEFORE THE EXPIRY DATE?

The Principal Investigator should take every precaution to ensure the research ethics approval does not lapse. The Principal Investigator should renew the study as soon as possible and provide the REB with a written explanation of the lapse as soon as possible, and confirm that no research-related procedures or actions occurred during the time in which there was no valid ethics approval.

In the case of lapsed clinical trials providing research-related medical care directly to participants, the Principal Investigator should provide the REB with a written explanation for the need to continue such medical care-related procedures, and confirm that no new participants were enrolled in the study during the lapse.

Failure to apply for the annual renewal prior to the expiry date on the current FHREB certificate may result in any of the following actions:

- Suspension of the financial account such that no further funds will be released until the study is renewed;
- Closure of the study (in which case a new submission would be required to re-activate the study);
- Notification of the Principal Investigator's Administrative Supervisor regarding the failure to comply with Fraser Health Research Ethics Policy requirements.