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 PROJECT

INTRODUCTION

The following notes, which comprise some of the Fraser Health Ethics Board's (FHREB) standard operating procedures and policies, are intended to ensure that the applicant has the necessary information to be able to complete the Integrated Post-Approval Application Form Section B - Renewals correctly.

The FHREB policies/procedures correspond to, and therefore comply with, the pertinent Tri-Council Policy Statement (TCPS) on 'Ethical Conduct for Investigator Involving Humans'[1], specifically TCPS 2, Article 6.14 which states:
"At minimum, continuing research ethics review shall consist of an annual status report (for multi-year research projects), and an end-of-study report (projects lasting less than one year)".

In addition, the ICH Good Clinical Practice Guidelines (ICH GCPs)[2] state in Article 3.1.4:
"The IRB/IEC should conduct continuing review of each ongoing trial at intervals appropriate to the degree of risk to human participants, but at least once per year".

Both of these documents have their origin in the ethical principles that were developed in the Declaration of Helsinki.[3] The FHREB operates under the authority of the FH Policies "FH Research" [Approved 2005 June 20] and "The Ethical Conduct of Research and Other Studies Involving Human Participants" [Approved 2005 April 12].

These Guidance Notes are not meant to be a substitute. Please refer to the original documents for complete information.

GUIDANCE NOTE #1: WHAT RESEARCHERS NEED TO KNOW TO SUBMIT A REQUEST FOR RENEWAL

Obligations of the Principal Investigator

The Principal Investigator is responsible for understanding and adhering to the TCPS 2 and other relevant guidelines.

Current FHREB Policies on Consent Form Requirements

The annual review conducted by the FHREB includes ensuring that any consent forms used in the study under review reflect the current policies of the FHREB with respect to consent form requirements. Modifications may be requested in cases where the consent form language does not adhere to current standards.

Expiry Dates of Studies

The initial FHREB approval for a research study is for a **one-year term** only, such that the approval expires on the one-year anniversary date of the original approval date. The FH REB approval for a study must be renewed on an annual basis. Subsequent renewals also expire on the one-year anniversary date of the approval for renewal.

Amendments approved after the initial approval/renewal date, also expire at the same time as the initial approval/renewal of the study.

[1] Canada: Tri-Council Policy Statement: Ethical Conduct for Investigator Involving Humans. August 1998. http://ncehr-cnerh.org
[2] Canada: Good Clinical Practice: Consolidated Guideline. ICH Harmonised Tripartite Guideline. 1997. http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/guides/ich/efficacy/goodclin_e.pdf .
[3] World Medical Association: Declaration of Helsinki. http://www.wma.net/e/policy/17-c_e.html

See below for clarification regarding particular types of studies.

Studies That Involve Human Participants

All clinical research studies that have received initial approval from the FHREB must be resubmitted to the FHREB prior to the approval expiry date if:

1) the research study is open to accrual/enrolment, or;
2) the research study is closed to accrual/enrolment but the participants are still participating in research procedures that have been specified in the protocol, such as ongoing follow-up.

Participants already enrolled in the study may continue to receive the study intervention while the renewal application is processed, even if the initial approval/subsequent renewal has expired as their participation is covered by the initial approval.

Enrolling new participants after the expiry date of the initial approval/subsequent renewal can only begin once the application has been approved and a Certificate of Approval: Annual Renewal is issued to the researcher.

Studies That Do Not Involve Participants

Studies that do not involve direct participant participation, for example, secondary use of data, must be submitted for renewal up until the point that the data acquisition is completed.

Ongoing Renewal

Annual renewal of studies may always continue at the request of the investigator. This may occur, if for example, the investigator believes that there may be a future need to obtain more data for a research project.

Timelines for Submitting Renewal Requests

The FHREB endeavors to keep current with international and national best practices in ethical review, and to be comparable with other jurisdictions that conduct ethical review. As a result of the FHREB's review of this type of information in addition to recommendations and/or questions that arise from researchers themselves, the FHREB may decide to revise its requirements with respect to standard wording in consent forms. When this occurs, the consent form template is revised and posted to the Research website at http://research.fraserhealth.ca/media/20090714ConsentFormRequirements.doc

Upon submission of a consent form for renewal, therefore, the FHREB will require the consent to be revised to reflect any necessary changes to the standard wording. This would be communicated in a memo from the FHREB.

In order not to affect participant enrollment into ongoing studies, please ensure that the submission for renewal is made well in advance of the date of expiry [i.e. a minimum of 4 - 6 weeks] so that if there are requests for modifications arising from either full or expedited review, these can be addressed in a timely fashion by the principal investigator.

Simultaneous Submission of Amendments

Amendments may be submitted with, and will be reviewed at the same time, as a request for renewal, using the 'Integrated Post-Approval Application Form.'

The Certificate of Annual Renewal may include the approval of any amendments if these were submitted at the same time as the request for annual renewal, or the amendment may be processed separately from the renewal.

Notification of Study Completion - Refer to the GUIDANCE NOTES FOR NOTIFICATION OF STUDY CLOSURE.

Updated 2017 November 17: Any request for renewal must be submitted using the 'Integrated Post-Approval Application Form'. TCPS 2, Article 6.14 states "As with initial review, continuing ethics review could be full board review or delegated review based on the level of risk of the research". All submissions may be emailed to REB@fraserhealth.ca or the current FHREB Coordinator.

2.1 Delegated Approval

The TCPS 2, Article 6.12 stipulates that when "it is determined that the research is of minimal risk…, an REB may authorize a delegated research ethics review in accordance with its institutional policies and written procedures". If this criterion is met, the Chair (or designate) will review the request for approval under the category of 'Delegated Review'. At the present time, the FHREB co-Chairs are responsible for reviewing applications for renewal.

The co-Chairs (or designate) can at any time put a request for annual renewal forward to the Full Board.

2.1.1 Timelines for Delegated Review

2.1.1.1 Review

Renewal applications are reviewed usually on a weekly basis. The time from submission of a renewal application to review will vary according to the volume of submitted renewals as well as amendments.

2.1.1.2 Issuing FHREB Decisions

All decisions arising from the review are emailed to the contact person identified in the Application Form.

Certificates of Approval for approved renewal applications are usually issued within one business day from the decision of the co-Chair. A pdf certificate with the digital signature of the co-Chair is emailed to the contact person and is the FHREB's official notification of the decision.

Modification memos are emailed usually within one business day from the decision of the co-Chair.

2.2 Full Board Review

Some institutions and sponsors may require that the Full Board review their submission for annual renewal. If this is the case, please specify this in the application and submit the required number of copies of relevant documentation [see GN 3.1].

2.2.1 Studies sponsored by the United States Department of Health and Human Services

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).

Refer to the following link for guidance on the interpretation of 45 CFR 46.109 (e) as it applies to studies sponsored by the DHHS.
http://www.hhs.gov/ohrp/policy/continuingreview2010.html#

This link can also be used to access the relevant articles under 46 CFR.

2.2.1.2 Studies sponsored by other United States federal agencies (updated 15 November 2003)

Studies that are funded by other American federal agencies (e.g. United States Department of Defence) may require Full Board Review under 21 CFR 56.110.

Refer to the following link for guidance on the interpretation of 21 CFR 56.110 as it applies to studies with this funding source.
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.110

2.2.2 Timelines for Full Board Review

The FHREB meets on the second Wednesday of each month. Submissions must be received by the FH Research Ethics Office three weeks in advance.

2.2.2.1 Issuing FHREB Decisions

All decisions arising from the review are emailed to the contact person identified in the Application Form and the Principal Investigator.

Certificates of Approval for approved renewal applications are usually issued within one to three business days from the date of the board meeting. A pdf certificate with the digital signature of the co-Chair is emailed to the contact person and is the FHREB's official notification of the decision.

Modification and deferral memos are emailed usually within five business days from the date of the board meeting.

GUIDANCE NOTE #3: REQUIRED DOCUMENTATION

Ensure that the necessary documents are submitted, as incomplete submissions will not be reviewed and it will be necessary to resubmit.

NB: As of January 2009 all consent forms will have the FHREB Approval date stamp.

For studies submitting consent forms, ensure that the consent form is the most recently approved version (check to ensure that the correct version number/date is on every page of the consent form). All approved consent form(s) will be electronically stamped with the FHREB approval date and returned via email with the renewal certificate of approval.

It is not necessary to resubmit the protocol, most recent versions of Investigator Brochures, advertisements, letters of initial contact or questionnaires/tests/interview scripts, if updated since the original approval, provided these have been previously reviewed and are listed in a previously issued Certificate of Approval (i.e. for amendment).

3.1 Full Board Review

Submit the signed 'Integrated Post-Approval Application' form and the most recently approved consent form(s).

3.2 Delegated Review

Submit the signed 'Integrated Post-Approval Application' form and the most recently approved consent form(s).

3.3 Exceptions for Studies Closed to Accrual/Enrolment with Participant Follow-up

The current version of the consent form(s) does not have to be submitted if the study has been closed to accrual/enrollment, and particpants are on follow up. Please make this information explicit in the Application Form and state when the study closed its enrolment.

3.4 Certificate of Annual Renewal

The approval date on the Certificate(s) of Annual Renewal will be the one-year anniversary of the original approval/subsequent renewal date.

Industry sponsors/institutions that require renewal at a particular time before the expiry date must submit their application for renewal before this required date.

The Certificate of Annual Renewal will not be backdated for any reason.

If the request for renewal is approved after the expiry date, the Certificate of Approval will be dated with the date on which the request for renewal was actually approved by either the FHREB or the co-Chair.

GUIDANCE NOTE #4 PRINCIPAL INVESTIGATOR SIGNATURE

If a Principal Investigator is not available to sign the Application Form before submission, the renewal may be submitted with a note stating that the signed and dated signature page (i.e. page will be sent to the FH Research Ethics Office and by when). The review of the renewal will not be delayed if the Principal Investigator's signature cannot be obtained by the time of submission.

GUIDANCE NOTE #5 CONTACT PERSON

All Certificates and Notices are emailed only to the contact person specified in the Application Form and copied to the Principal Investigator.

GUIDANCE NOTE #6 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. Remarks about the ability to recruit participants are also appropriate as is any information about the results from any interim analyses.

GUIDANCE NOTE #7 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.