

Research & Performance Support  
Regina Qu'Appelle Health Region  
2180-23<sup>rd</sup> Avenue Regina SK S4S 0A5  
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## Guidelines for the Application Requesting Amendment of a Previously Approved Project

### INTRODUCTION

The RQHR Research Ethics board policies/procedures correspond to, and therefore comply with, the pertinent Tri-Council Policy Statement (TCPS) on 'Ethical Conduct for Research Involving Humans'<sup>1</sup>, specifically Article 1.13 (a) which states that "Ongoing research shall be subject to continuing ethics review. The rigour of the review should be in accordance with a proportionate approach to ethics assessment".

With respect to clinical trials, the ICH Good Clinical Practice (ICH GCP) Guidelines<sup>2</sup> Article 3.3.7 states:

**"...no deviations from, or changes of, the protocol should be initiated without prior written IRB/IEC approval/favourable opinion of an appropriate amendment, except when necessary to eliminate immediate hazards to the subjects or when the change(s) involves only logistical or administrative aspects of the trial (e.g. change of monitor(s), telephone numbers(s))".**

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

### GUIDELINES

#### Obligations of the Principal Investigator

The Principal Investigator for a study is responsible for ensuring that amendments are submitted to the REB prior to implementation and for understanding and adhering to the TCPS and other relevant guidelines, including ICH GCP when applicable. In particular, ICH GCP 4.5.2 specifies that:

**"The investigator should not implement any deviation from, or changes of the protocol without agreement by the sponsor and prior review and documented approval/favourable opinion from the IRB/IEC of an amendment..."**

#### Studies Requiring Amendment Before Initial Approval Is Obtained

Amendments should only be submitted for review AFTER the study has received initial approval from the REB.

#### Approval Period for Amendments

The term of the approval for the amendment expires at the same time as the initial approval/annual renewal for the study.

#### Change of Investigator or Contact Person's Contact Information

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<sup>1</sup> Canada: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. August 1998. Available at <http://ncehr-cnerh.org>

<sup>2</sup> Canada: Good Clinical Practice: Consolidated Guideline. ICH Harmonised Tripartite Guideline. 1997. Available at <http://www.ncehr-cnerh.org/english/gcp/>

Submit changes to any of the investigator's/contact person's contact information (i.e. address, telephone/fax number, email) by email/letter to the REB office (Research and Performance Support). Ensure that all studies affected by the change(s) are specified in the letter. See below for additional information about a change of principal investigator. The REB office will send an acknowledgement to the designated contact.

### **Expedited Review**

The TCPS Article 1.6 stipulates that the REB can delegate the authority for the approval of amendments to the Chair (or designate) of the REB under the category of 'Expedited Review'. Most amendments can be reviewed under the Expedited Review process. Refer below to "Full Board Review" for criteria that designate which type of amendments must receive Full Board review. The Chair (or designate) may at any time put forward a request for approval of an amendment to the Full Board.

### **Review Process**

Amendments are reviewed usually on a weekly basis. The time from submission of an amendment to review will vary according to the volume of submitted amendments as well as renewal applications. All decisions **arising from the review are sent to the primary investigator unless another individual is identified in Box 17** of the Application Form.

### **Full Board Review (Box 5)**

The following types of amendments for previously approved studies that are clinical trials [drug, device, natural health product] must be referred to the Full Board for review as required by Health Canada.

1. Addition of genetic testing, new genetic tests or tissue banking where genetic testing may or will be performed;
2. Addition of an open label extension phase following a randomized trial;
3. Emergency amendments that arise because of subject safety concerns and that are submitted after implementation as a result, and;
4. Significant changes to a protocol that may affect subject safety and may include a (but are not limited to):
  - i) change in drug dosing/duration of exposure,
  - ii) decrease in monitoring,
  - iii) change in recruitment technique that may affect confidentiality or the perception of coercion,
  - iv) change in experimental procedure or study population.

\*See the ***Guidance Notes for RQHR Research Ethics Board Application Form*** document for further information on which studies require full board review.

### **Change of Principal Investigator (Box 6)**

This is considered an administrative amendment and does not affect the ongoing enrolment of subjects. The new Principal Investigator signs the Amendment Form in Box #18 so that the appropriate contact information is included for the new Principal Investigator and so that there is documentation of the new Principal Investigator's attestation to abide by the Tri-Council Policy as stated in Box 18.

In addition, the new Principal Investigator must declare any potential conflict of interest that could arise from assuming this role (see **Box 15** on Amendment Form). An updated Certificate of Approval will be issued to the newly designated Principal Investigator only.

### **New Study Titles (Box 9)**

Changes to study titles must also be submitted using the amendment application form. This information is important to ensure that the title on a Certificate of Approval coincides with the correct funding agency as there may be somewhat different study titles for different funding agencies.

### **Changes to Funding Agency (Box 11)**

Submit any changes regarding who is funding the study and/or name changes of funding agencies (e.g. when the funding agency's name is changed from Roche Products Ltd. to Hoffmann-LaRoche Limited). When ANY funding agency is changed/renamed, a revised consent form is also required and must be submitted with the

application. See also **Box 15** to describe any potential conflict of interest that might result from a change of agency.

### **Summary of Amendments (Box 13)**

For both Full Board and Expedited Review, the REB reviewers require a list and summary of the nature of any previous amendments so that it is easy to track how the study has been amended over time. This summary should include only those amendments that had been submitted either after the initial approval or subsequent annual renewal (i.e. amendments submitted within the approval period for the entire study; this may be between the date of initial approval to submission for initial renewal OR between the date of subsequent annual approval for renewal to submission of the next request for annual renewal).

### **Additional Information About Risks**

The notification of a new risk(s) must be documented in a revised consent form for new subjects. Depending on the nature of the risk the REB may require that subjects already enrolled in the study be re-consented.

### **Submission Process**

All necessary documents must be submitted with the correct number of copies required for either Full Board Review (19) or Expedited Review (1). Incomplete submissions will not be reviewed and will have to be resubmitted.

Amended documents must be submitted in such a way that any changes are clearly identified. *Protocol* amendments may include a separate document that lists both the original section(s) and the subsequent revision(s) so changes to the original text are easily seen.

Submit the amended *consent form* with the changes underlined or in **bold text** so that it is easy to see how the original consent form has been altered. The amended consent form should include a footer with an updated version number and/or date.

Documents listed in **Box 12** of the Application Form must be recorded accurately with their complete title and version numbers because this information is included in the amendment box of the certificate.

The Amendment Application and attached documents (all copies) are submitted to the ***Research Ethics Board, Research and Performance Support, 2180-23rd Avenue, Regina, SK, S4S 0A5.***



Research & Performance Support  
 Regina Qu'Appelle Health Region  
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For Administrative Use Only:	
File Number: _____	Date Received: _____
Expiry Date of current certificate of approval: _____ (MM/DD/YY)	

## Application Requesting Amendment of a Previously Approved Project

*All information requested must be typewritten in the space provided. Do not leave any box blank. Indicate "not applicable" by typing N/A.*

<b>1. PRINCIPAL INVESTIGATOR</b>	<b>Name:</b> <b>Address:</b> <b>Phone:</b> <b>Fax:</b> <b>Email:</b>
<b>2. RQHR PROJECT #</b>	REB -
<b>3. PROJECT TITLE, PROTOCOL #</b>	
<b>4. SPONSOR</b>	

<b>5. Please indicate whether you require FULL BOARD REVIEW.</b> <input type="checkbox"/> Yes <input type="checkbox"/> No	
<b>6. Add <input type="checkbox"/> New Principal Investigator</b>  <b>Name:</b> <b>Address:</b> <b>Phone #:</b> <b>Fax #:</b> <b>Email:</b> <b>RQHR Staff Position:</b> <b>Hospital Department:</b> <b>Hospital Division:</b>	
<b>7. Add <input type="checkbox"/> or Delete <input type="checkbox"/> Co-Investigator</b>  <b>Name:</b> <b>RQHR Staff Position:</b> <b>Hospital Department:</b> <b>Hospital Division:</b> <b>University Faculty/Dept. (if applicable):</b>	<b>8. Add <input type="checkbox"/> or Delete <input type="checkbox"/> Co-Investigator</b>  <b>Name:</b> <b>RQHR Staff Position:</b> <b>Hospital Department:</b> <b>Hospital Division:</b> <b>University Faculty/Dept. (if applicable):</b>

**9. Change  Project Title**

**Amended Title of Project:**

**Project Period: From:** (MM/DD/YY) to (MM/DD/YY)

**10. Have there been any changes to the sites where the research is being carried out?**

- No  
 Yes If Yes, please give details:

**11. Have there been any changes to the funding agency?**

- No  
 Yes If Yes, please give details and complete Box 15:

**12. Please indicate amended items. If expedited, submit ONE copy of each; Full Board Review-submit 19 copies. Use bold type/underline to show changes in documents; list version numbers and/or dates.**

***Amended Documents***

***Description & Version number/date***

- Protocol Amendment  
 Advertisement to recruit subjects  
 Letter of initial contact  
 Consent form  
 Assent form  
 Questionnaires, tests, interview scripts, etc.  
 Other

**13. List and summarize any amendments to this study that have been previously approved since the date of approval of the most recent certificate of approval and/or renewal.**

**14. Describe any changes to the study for which you are seeking approval in this application.**

**15. Describe any potential conflict of interest as a result of a change in principal investigator or funding agency.**

**16. Additional Information.**

**17. The certificate of approval or notice of ethical review for the amendment will be mailed/emailed to the primary investigator unless another individual's contact information is completed below.**

**Name:**

**Title:**

**Phone:**

**Fax:**

**Email Address:**

**Address:**

**18. Principal Investigator: *I agree to abide by the Tri-Council Policy for Ethical Conduct for Research Involving Human Subjects.***

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date (MM/DD/YY)

**For Administrative Use Only:**

\_\_\_\_\_  
REB Chair Signature

\_\_\_\_\_  
Date (MM/DD/YY)