**Guidance Notes**

**For the Application Requesting Amendment of a Previously Approved Project**

# INTRODUCTION

The Research Ethics board policies/procedures correspond to, and therefore comply with, the pertinent Tri-Council Policy Statement (TCPS 2, 2018) on ‘Ethical Conduct for Research Involving Humans’[[1]](#footnote-1), specifically Article 2.8 which states that “[f]ollowing initial REB review and approval, research ethics review shall continue throughout the life of the project…”.)

With respect to clinical trials, the ICH Good Clinical Practice (ICH GCP E6) Guidelines[[2]](#footnote-2) 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.

# GUIDANCE NOTES

### 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 E6 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**

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 Department). 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 6.12 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 regular basis. The time from submission of an amendment to review will vary according to the volume of submitted amendments as well as renewal applications.

### 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):
			1. change in drug dosing/duration of exposure,
			2. decrease in monitoring,
			3. change in recruitment technique that may affect confidentiality or the perception of coercion,
			4. change in experimental procedure or study population.

\*See the ***Guidance Notes for 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).

### Changes being requested and Additional Information About Risks (Box 14 and 16)

The notification of 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 electronically. 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. Please submit a track changes and clean copy of all revised study documents.

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 (clean and track changes copies) are submitted to

Research Ethics SHA at ResearchEthics@saskhealthauthority.ca

**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.*

|  |
| --- |
| PART 1: Identification |
| 1. | Project Title      Protocol Number (if applicable):       |
| 2. | Principal Investigator Full Name:      Mailing Address:      Email:      Phone:       |
| 3. | REB Project #: REB-      |
| 4. | Sponsor:       |
| 5. | **Please indicate whether you require FULL BOARD REVIEW.****[ ]**  Yes **[ ]**  No |
| 6. | Add New Principal Investigator Full Name:      Mailing Address:      Email:      Phone:      Position:      Hospital Department:      Hospital Division:      University Faculty/Dept. (if applicable):       |
| 7. | Add [ ]  or Delete [ ]  Co-Investigator Full Name:      SHA Staff Position: Hospital Department:      Hospital Division:      University Faculty/Dept. (if applicable):       |
| 8. | Add [ ]  or Delete [ ]  Co-Investigator Full Name:      SHA Staff Position: Hospital Department:      Hospital Division:      University Faculty/Dept. (if applicable):       |
| 9. | **[ ]**  **Change Project Title**Amended Title of Project:      Project Period: From       to       (MM/DD/YY) |
| 10. | Have there been any changes to the sites where the research is being carried out?[ ]  Yes [ ]  NoIf yes, please provide details:       |
| 11. | Have there been any changes to the funding agency?[ ]  Yes [ ]  NoIf yes, please provide details and complete Box 15:       |
| 12. | Please indicate amended items. Submit one copy of each document electronically. Use track changes to show changes in documents; list version numbers and/or dates. |
| **Amended Documents****[ ]  Protocol** **[ ]  Amendment** **[ ]  Advertisement****[ ]  Letter of Initial Contact** **[ ]  Assent Form****[ ]  Questionnaires, tests, interview scripts, etc.****[ ]  Other** | **Description & Version Number/Date** |
| 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 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 emailed to the Principal Investigator unless another individual’s contact information is completed below. Full Name:      Full Name:      Mailing Address:      Email:      Phone:       |
| 18. | **Declaration by Principal Investigator:** I agree to abide by the Tri-Council Policy for Ethical Conduct for Research Involving Human Subjects.            Signature of Principal Investigator Printed Name of Principal Investigator Date (MM/DD/YY) |
| **For Administrative Use Only:** REB Chair Signature Date (MM/DD/YY) |

1. Canada: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. 2014. Available at <https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html> [↑](#footnote-ref-1)
2. Canada: Good Clinical Practice: Consolidated Guideline. ICH Harmonised Tripartite Guideline. 2016. Available at <https://www.ich.org/page/efficacy-guidelines> [↑](#footnote-ref-2)