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## GUIDANCE NOTES FOR REQUEST FOR AMENDMENT OF A PREVIOUSLY APPROVED PROJECT – BCCA REB

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### INTRODUCTION

The following notes are intended to assist researchers with completion and submission of a Request for Amendment of a previously Approved Project form.

The Tri-Council Policy Statement, the ICH-GCPs and the US Federal Regulations all require researchers to submit proposed changes to previously approved research projects to the Research Ethics Board for approval. ALL changes must be submitted **prior** to the changes being implemented, “except when necessary to eliminate immediate hazards to subjects or when the change(s) involve minor administrative changes such as changes in granting status, staff personnel, contact person or phone number etc”. The REB must be informed of any such changes, as soon as possible after the change has been made, together with information concerning the rationale for such actions. All such changes must be formalized by the subsequent filing of a Request for Amendment.

An amendment may be defined as a permanent intentional action or process that revises/amends/modifies a previously approved research protocol. If researchers are changing any part of a study, regardless of whether it is merely an “administrative” or “minor” change an amendment must be submitted.

Amendments for approved Clinical or Behavioural research projects must be submitted to the board of record for that project

### ARTICLE # 1: WHAT RESEARCHERS NEED TO KNOW PRIOR TO SUBMITTING A REQUEST FOR AMENDMENT

#### 1.1 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 \(E6\) Guidance for Industry \(pdf\)](#) when applicable. In particular, [ICH GCP Article 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, except where necessary to eliminate an immediate hazard(s) to trial subjects, or when the change(s) involves only logistical or administrative aspects of the trial (e.g., change in monitor(s), change of telephone number(s))....”**.

## 1.2 Studies Requiring Amendment Before Initial Approval Is Obtained

Amendments may only be submitted for review AFTER the study has received initial approval from the REB. (Some amendments [changes] may be submitted with a response to proviso or deferral of the initial study submission. If the PI receives an "amended protocol" from the sponsor between the time the new study was submitted to the REB and prior to REB approval, they should contact the REB for instructions on how to proceed.) Only one RISE amendment application can be submitted at a time. (You will not be able to submit a second amendment application form until the first one is approved by the REB. However, a single amendment submission may contain more than one "protocol amendment" and/or other changes.)

## 1.3 Amendments Submitted With a Request for Annual Renewal

For studies submitted to one of the UBC REB's (such as the UBC BC Cancer Agency REB) where the "Annual Renewal with Amendments to Study" form option is not available, a Request for Amendment form and a separate Request for Annual Renewal form may be submitted simultaneously and may be marked individually for expedited or full board review.

## 1.4 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. (In other words, approval of an amendment does not renew the study; it will still expire on the expiry date and can only be renewed by submitting a separate request for Annual Renewal form.)

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

Changes to any of the investigator's/contact person's contact information (i.e. address, telephone/fax number, email) in the individual's RISE profile must be updated by that person in RISE by updating their own Profile. See [Article #3](#), below for additional requirements for a permanent or temporary change of principal investigator. or co-investigator.

## 1.6 Whom to Contact For Assistance:

Questions regarding the preparation of an Amendment submission should be submitted to the UBC REB that approved the project (the "Board of Record" for the study):

**BC Cancer Agency Research Ethics Board** - (604) 877-6223 or (604) 877-6283, or email [reb@bccancer.bc.ca](mailto:reb@bccancer.bc.ca)

**Providence Health Care Research Ethics Board** - (604) 682-2344 ext. 63496 or email [VBearder@providencehealth.bc.ca](mailto:VBearder@providencehealth.bc.ca)

**UBC Clinical Research Ethics Board** - (604) 875-4111 ext.68917 or email [creb.rise@ors.ubc.ca](mailto:creb.rise@ors.ubc.ca)

**UBC Behavioural Research Ethics Board** – (604) 827-5114 or email [nadia.rad@ors.ubc.ca](mailto:nadia.rad@ors.ubc.ca)

**Children & Women's Health Centre Research Ethics Board** – (604) 875-3103 or email [cwreb@cw.bc.ca](mailto:cwreb@cw.bc.ca)

UBC Okanagan Research Ethics Board – (250) 807-8832 or email [Kristen.kane@ubc.ca](mailto:Kristen.kane@ubc.ca)

## ARTICLE #2 LEVEL OF REVIEW

### 2.1 Delegated / Expedited Review

[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. UBC REB policies allow for delegated review at the discretion of the REB Chair, in circumstances where the proposed amendment does not involve increased risks to the study participants such that the study would no longer meet the criteria for minimal risk.

#### 2.1.1 Criteria for Minimal Risk

The criteria for minimal risk in relation to **clinical studies** are described in the CREB Guidance Notes 2.1

[http://rise.ubc.ca/helpCenter/GN/CREB\\_Guidance\\_Notes.html#Guide2.1](http://rise.ubc.ca/helpCenter/GN/CREB_Guidance_Notes.html#Guide2.1)

The criteria for minimal risk in relation to **behavioural studies** are described in the BREB Guidance Notes 4.6.

<http://www.ors.ubc.ca/ethics/behavioural/b-forms.htm>

**For US FDA or US Federally funded or supported research**, only minor changes (as defined below) in previously approved research may be reviewed by the REB under delegated review procedures (expedited review). The REB Chair (or designate) may at any time put forward a request for approval of an amendment to the Full Board

#### 2.1.2. Minor Changes

Minor changes may be defined as those that do not materially affect an assessment of the risks and benefits of the study and do not substantially change the specific aims/design of the study.

### 2.2 Criteria for Full Board Review

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.
5. Any amendment that requires approval from Health Canada  
Amendments that require Health Canada Approval must be submitted to the REB for **full board** review and a copy of the Health Canada No Objection Letter for the amendment must be received by the REB

prior to the REB issuing the Certificate of approval. The copy of the Health Canada No Objection Letter must be submitted in RISE by attaching it to Section 9 of the application form.  
(See [Health Canada Approval of Amendments](#) ) (Also see [Policies: Certificates of Approval](#))

### ARTICLE #3: CHANGE OF PRINCIPAL INVESTIGATOR

It is advisable that once a study is approved, the principal investigator should immediately designate up to two co-investigators with signing authority in RISE from the list of approved co-investigators in the study application who may act on their behalf (this does not require submission to the REB). [Designate Co-investigators with Signing Authority in RISE.](#)

The BCCA REB requires notification when there is a permanent, or a temporary change of any investigator on the study who will be relinquishing their duties for 6 (six) months or longer.

In order to permanently or temporarily change the Principal Investigator, the original Principal Investigator must submit a signed form (located in RISE in the PAA Coversheet Question #1.3 of the 'Amendments to Study' form) requesting the change to the new Principal Investigator. The letter must be signed by the original principal investigator, the new principal investigator and their department head. The signed form includes the new PI's attestation to abide by the TCPS and a declaration of any potential conflict of interest that could arise from assuming this role. This also includes attestation from the Department Head that the new PI has the qualifications, experience, and facilities to carry out this research. If the original PI is not available to submit the amendment in RISE, contact the applicable REB for assistance.

Updated study documentation (i.e. informed consent form) and an updated Application Form is required so that the appropriate contact information is included for the new PI.

A Certificate of Approval of Amendment will be posted on the RISE study homepage, as well as within the Amendment submission in RISE.

### ARTICLE #4: ADMINISTRATIVE AMENDMENTS AND EDITS TO THE INITIAL APPLICATION

**Changes to co-investigators, study personnel, site changes** (added or removed), changes to funding agencies and changes to study titles are considered administrative amendments. **All such changes to the study must be submitted to the REB as an amendment and the change should be entered into the appropriate sections of the RISE application with any applicable revised documents.**

**ANY change to the funding agency** (e.g. when the funding agency's name is changed from Roche Products Ltd. To Hoffmann-LaRoche Limited) REQUIRE the submission of a revised consent form.

**When a study is given a new title**, the application form and all study documents should be updated to reflect the change. The name of the new title entered in Section 1.7 will be reflected on the Certificate of Approval of Amendment. The UBC Office of Research Services will only release specific project funds to the Investigator if the Certificate of Approval includes the funding agency that matches the correct study title. If a project title specific to a funding agency needs to be added (that is different from the main project title entered in Section 1.7), it may be added in Section 2.3 or Section 2.4 of the RISE application as per the section's instruction in RISE. Section 2.3 and 2.4 of the RISE application also populate into the certificates of approval.

**Amendments that require Health Canada Approval** must be submitted to the REB for **full board** review and a copy of the Health Canada No Objection Letter for the amendment must be received by the REB prior to the REB

issuing the Certificate of approval. **The copy of the Health Canada No Objection Letter must be submitted** in RISE by attaching it to Section 9 of the application form. Before submitting the document; if the letter does not identify the specific protocol to which it applies then write the protocol number (or similar reference) on the letter so it is clearly linked to the specific protocol, then initial the document, and attach it to the RISE application. (See [Health Canada Approval](#)) (Also see [Policies: Certificates of Approval](#))

**Amendments to the Clinical Trial Agreement (Legal Contract)**, must be submitted to the REB as an amendment (attach to Section 9 of the RISE application). (See [Policies: Clinical Trial Agreement](#) )

## ARTICLE #5 THE SUBMISSION PROCESS

### 5.1. General Requirements

All necessary documents must be submitted. 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 as to what is being changed, the rationale for the change, and specific references to where the changes are made (i.e. in the RISE application and/or documents). All amended documents must be attached in Section 9 of the revised initial application form. Revised documents must be marked in a way that the changed text can be identified (use either highlights or the track changes feature of Word) , and should include an updated version date in the footer.

### 5.2. Protocol Amendments

Protocol amendments should include a separate document (summary of changes) that lists both the original section(s) and the subsequent revision(s), and the rationale for the change, so changes to the original text are easily seen and explained. If a summary is not submitted, the amended protocol must be explained in the application and the document must be marked in such a way that any changes are clearly identified.

### 5.3. Amended Consent Forms

Submit the amended consent form with the changes **highlighted or use the track changes feature of Word**, so that it is easy to see how the original consent form has been altered. The amended consent form should include an updated version date in the footer of the document (and ensure that the date entered in the RISE application matches the document date).

### 5.4. Updated Investigator Brochures and Safety Data Reports **(revised Oct 30/09)**

An updated Investigator Brochure (IB) must be accompanied by documentation that summarizes the changes to the IB. Confirm that no changes to the protocol or consent are required, or if changes are required to the protocol and/or consent, provide details of the changes, rationales for each change, where the changes have been made in the documents, and attach the revised documents. If the required the changes have already been completed on a previous or concurrent amendment, provide the PAA number.

Safety Data Reports submitted as an amendment must be accompanied by a summary of the report(s) with the applicable revised documents and appropriate changes to the RISE application.

### 5.5. Documents Listed on Certificates of Approval

Documents attached to Section 9 of the revised initial Application Form must be recorded accurately with the document name and version numbers because this information is populated by RISE into the Certificate of Approval and due to security features of RISE, the REB cannot edit these for the applicant.

### 5.6. Timelines for Submission

Refer to the links on your homepage in RISE for the REB schedules of meetings and submission deadlines for amendments that require full board approval. Amendments that meet the criteria for delegated (expedited) review may be submitted at any time. The BCCA REB deadlines and meeting schedule is posted on the BCCA REB web page: <http://www.bccancer.bc.ca/RES/REB/Mtgs.htm>

### 5.7. Issuing REB Decisions

All decisions arising from the review are emailed by RISE to the Principal Investigator and the Primary Contact person identified in Question #1.2 of the Application Form. An Approval Certificate is displayed on the study homepage in RISE, as well as in the Amendment submission, and is the REB's official notification of the decision.

## ARTICLE #6: SUMMARY OF THE AMENDMENT

Briefly describe the nature of the proposed change(s) (what is being changed), the reason (why) it is being changed, and indicate (where) in the study application or documentation the changes are made. Also explain whether or not the change will result in any increase in risk or discomfort for the study participants. If it will, explain what these are and why they are required.

Describe any changes to the study, involving the study's objectives, research design, sample size, inclusion/exclusion criteria, and/or changes to the treatment/intervention procedures/dosage and explain how any changes will affect the study.

Describe any changes to consent form(s) (and any other documentation, such as advertisements/information sheets, questionnaires) in this section of the Application Form as well.

## ARTICLE #7: RECONSENT

If the change requires a revision to the informed consent, Include information on how the subjects (who are already enrolled) will be contacted and how the new information about their participation in the study will be given to them.

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(s), the REB may require that subjects already enrolled in the study be reconsented.

The REB may request that subjects already enrolled are either notified by letter or reconsented when significant changes are made in the sponsorship of the research.

For studies that involve tissue/DNA banking, when the sponsor has changed, or a different storage facility is used to store the subjects' specimens, subjects should either be reconsented or informed of the change to the study via a letter, which gives the subjects the opportunity to withdraw their tissue from storage should they have any concerns.

#### **ARTICLE #8: DEVIATIONS FROM INFORMATION PROVIDED TO THE REB**

Once an amendment is approved any deviation from the information provided in the amendment approved by the REB must be reported to the REB (e.g., if the investigator indicates in an amendment that already enrolled subjects will be reconsented and then does not comply with this statement, this should be reported to the REB with an explanation in a Request for Acknowledgment form in RISE.)

See [UBC BCCA REB Policy re Protocol Deviations](#)

#### **ARTICLE #9: POST APPROVAL ACTIVITY (PAA) "NICKNAME" REQUIRED**

When creating a new Post-Approval Activity (PAA) in RISE, enter a "PAA nickname" to identify the content of the amendment or acknowledgment. (*This is separate from the "study nickname"*).

See [Post Approval Activity \(Paa\) "Nickname"](#)