RR0400—AMENDMENTS

1.0 PURPOSE

To provide direction for the responsibilities of the researcher and the Interior Health (IH) Research Ethics Board (REB) when a there is a change to the research protocol, application procedures or research staff is proposed.

2.0 DEFINITIONS

Term	Definition
Amendment	A written description of a change(s) to the previously approved research project. Amendments include any changes to the protocol or related research documents.
Continuing Ethics Review	REB review of ongoing research occurring after the date of initial REB approval and continuing throughout the life of the project to ensure that all stages of a research project are ethically acceptable in accordance with the principles of the Tri-Council Policy Statement.

3.0 POLICY

3.1 Researcher:

3.1.1 **T**he researcher is responsible for submitting to the REB any changes to the approved research in the form of an amendment application. Changes to the approved research may include modifications to the protocol, application, the consent form or other participant materials, the Investigator's Brochure or Product Monograph, a change in study team members, etc.

3.1.2 The researcher will not implement any amendment or change to a protocol or project without prior approval of the REB; **except** in a serious event where immediate action is required to eliminate harm to participants. In those cases, the researcher will inform the REB as soon as possible.

3.1.3 When the amendment includes a change to the consent form, the researcher must indicate his/her recommendation for the provision of the new information to current and/or past research participants.

3.1.4 The Amendment Application must clearly explain the following:

3.1.4.1 The nature of the proposed change;

3.1.4.2 The reason for the proposed change;

3.1.4.3 What aspects of the protocol or other study documents have been revised;

3.1.4.4 Any increase in risk or discomfort for study participants and why it is required;

3.1.4.5 Whether previously or currently enrolled participants need to be re-consented;

3.1.4.6 Any changes to the consent form or consent process;

3.1.4.7 Whether or not the amendment meets the criteria for delegated review.

3.2 REB

3.2.1 The REB will use a proportionate approach with review of amendments so that the level of review is commensurate with the level of risk. The REB reserves the right to provide full Board review for any amendment that poses greater than minimal risk to research participants.

3.2.2 The REB will provide full board review of any amendment which represents more than minimal risk to participants. This includes:

3.2.2.1 Any amendment that requires approval from Health Canada;

3.2.2.2 Any amendment to a study funded or regulated by the US Federal Government;

3.2.2.3 Addition of genetic testing, new genetic tests, or tissue banking where genetic testing may or will be performed;

3.2.2.4 Addition of an open label extension phase following a randomized trial;

3.2.2.5 Emergency amendments that arise because of participant safety concerns that are submitted after implementation; and

3.2.2.6 Significant changes to a protocol that may affect participant safety. This includes, but is not limited to:

3.2.2.6.1 Change in drug dose or duration of exposure

3.2.2.6.2 Decrease in monitoring

3.2.2.6.3 Change in recruitment technique that may affect confidentiality or the perception of coercion

3.2.2.6.4 Change in experimental procedure or study population

3.2.3 The REB must find that the criteria for approval are still met in order to approve the amendment.

4.0 PROCEDURES

4.1 Research Ethics Board Coordinator

4.1.1 Receives all amendment applications and determines the level of risk. Reviews and approves amendments which qualify for delegated review as delegated by the Chair.

4.1.2 Adds amendments requiring full Board review to the agenda for the next scheduled REB meeting.

4.1.3 Assigns amendments requiring full Board review to the original primary reviewers if possible, or to the Chair.

4.1.3 For projects not housed on the RISe platform, **a**dds the Amendment Application form and related documents to the project file.

4.1.4 Maintains a Tracking Tool on all amendments and circulates to the REB at the next scheduled meeting.

4.1.5 Issues Approval Certificate to the researcher for amendments that have been approved by full Board review, by the Chair, or by a qualified delegated reviewer. Approval Certificates for Amendments are issued for the remainder of the current approval term.

4.2 REB

4.2.1 Reviews, makes recommendations for changes to the project if required, and approves all amendments that require full Board review.

4.2.2 Primary reviewers for amendments requiring full board review will be the same as those REB members who were the primary reviewers for the initial review. If this is not possible, the Chair will lead the review

4.2.3 .

4.3 REB Chair

4.3.1 Reviews amendment applications of indeterminate risk status and makes a determination regarding whether the amendment qualifies for delegated review. If significant ethical concerns are identified, forwards the activity for full Board review at the next scheduled REB meeting.

4.3.2 If a delegated or full Board review results in recommendations for change, the Chair or delegate will communicate the recommendations to the researcher by issuing provisos.

4.4 Researcher

4.4.1 If the study is housed on the RISe platform, submits applications for amendments via the Post Approval Activities function; edits the RISe Application as needed and attaches all revised documents. If the application is not housed in RISe, the researcher will forward all relevant documentation to the REB via email, including

an updated version of the IH REB Application for Ethical Review form and all attachments.

4.4.2 Submits all revised documents in tracked changes mode. All revised documents must be dated and version noted.

5.0 REFERENCES

Canadian Association of Research Ethics Boards and N2 Network of Networks. (2019). Standard Operating Procedure 404.003: *Ongoing REB Review Activities.*

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2018.

Fraser Health Authority. (2014). Research and Evaluation Policy: *The Ethical Conduct of Research and Other Studies Involving Human Subjects*.

Health Canada, Food and Drug Regulations, Part C, Division 5, *Drugs for Clinical Trials Involving Human Subjects* November 28, 2017.

International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), ICH Harmonized Guideline, Integrated Addendum to ICH E6(R1); *Guideline for Good Clinical Practice*, E6(R2), November 9, 2016.

UBC Office of Research Ethics. (2018). Standard Operating Procedure 404: *Ongoing REB Review Activities.*

US Food and Drug Administration Code of Federal Regulations, Title 21, Volume 1:

- Part 56, Institutional Review Boards, (21CFR56, section 110).

**This policy replaces the following policies which are no longer active:
IH REB Policy: *RE0100 Amendments* approved March 6, 2008
IH REB Policy: *RE0600 Continuing Review* approved December 6, 2007

This policy was previously titled *Continuing Review*.