RR0500 – RENEWAL OF ETHICAL APPROVAL

1.0 PURPOSE

To provide direction for the annual renewal of ethical approval for research projects involving human participants that will continue beyond the Interior Health (IH) Research Ethics Board (REB) initial approval period.

2.0 DEFINITIONS

TERM	DEFINITION
Above Minimal Risk Research	Research in which the probability and magnitude of possible harms implied by participation in the research is greater than those encountered by participants in those aspects of their everyday life that relate to the research.
Delegated Review	The level of REB review assigned to minimal risk research projects, to minor changes in approved research and to continuing review applications that meet the delegated review criteria. Delegated reviewers are selected from the REB membership to conduct the review.
Full Board Review	The level of REB review assigned to above minimal risk research projects. Conducted by full membership of the REB, it is the default requirement for the ethics review of research involving human participants.
Initial Review	The review and approval of a research proposal for ethical acceptability prior to the start of recruitment of participants, access to data, or the collection of data.
Minimal Risk Research	Research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.
Renewal	Review and approval of the renewal of ethical approval for a project that continues on past the term of initial approval.

3.0 POLICY

3.1 The REB must establish procedures for conducting the continuing review and renewal of approval for research involving human participants at intervals appropriate to the degree of risk, but not less than once a year. Periodic review of research activities is necessary to determine whether approval should be continued or withdrawn.

RR0500 – RENEWAL OF ETHICAL APPROVAL

3.2 The REB may determine that the research requires continuing review more frequently than once per year by considering the following:

3.2.1 The nature of any risks posed by the research;
3.2.2 The degree of uncertainty regarding the risks involved;
3.2.3 The vulnerability of the participant population;
3.2.4 The projected rate of enrolment and estimated research closure date;
3.2.5 Whether the research involves novel interventions;
3.2.6 The REB believes that more frequent review is required.

3.3 The researcher is required to submit an application for continuing review of research at a frequency to be determined by the REB and which will be defined at the time of the initial approval of the research, or as otherwise revised.

3.4 At a minimum, the REB requires that an application for renewal be submitted once per year until all of the data has been collected, all contact with research participants has concluded and the closure of the research has been acknowledged by the REB.

3.5 The researcher is required to submit a Request for Renewal application form and related study documents (if applicable) with sufficient lead time to allow the REB to review the application, issue provisos as needed, and for the PI to respond to provisos prior to the expiry date of the current approval certificate.

3.5.1 For minimal risk reviews, the application form must be submitted to the Research Ethics Office (REO) a minimum of four weeks before the expiry date of the current approval certificate;

3.5.2 For Renewal Requests that require full board review, the application must be submitted to the REB meeting that precedes the expiry date of the current approval certificate by at least four weeks. Meeting dates and submission deadlines are posted on the REB website.

3.6 The REB will use a proportionate approach with continuing review activities 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 renewal that poses greater than minimal risk to research participants.

3.7 To grant a continuation of the approval of the research the REB must determine that:

3.7.1 There have been no material changes to the research or to the informed consent form that have not been previously submitted and approved;
3.7.2 There is no new conflict of interest or new information that has emerged that might adversely affect the safety of the well-being of research participants;
3.7.3 Risks to research participants are minimized and reasonable in relation to the anticipated benefits;
3.7.4 Selection of research participants is equitable;

3.7.5 Informed consent processes continue to be appropriate and documented;
3.7.6 Adequate provisions are in place for monitoring and data protection to ensure the safety and privacy of participants and the confidentiality and integrity of the data;
3.7.7 Any complaints from research participants have been followed up appropriately.

3.8 The REB may also make additional determinations, including:

3.8.1 Request changes to the informed consent form(s);
3.8.2 Request changes for the continuing review interval (based on risks);
3.8.3 Impose special precautions (e.g. frequency of monitoring, requirement of interim reports or change in duration of approval period);
3.8.4 Require modifications to the research.

3.9 The REB may request verification from sources other than the researcher that no material changes have occurred since previous REB review. These sources may include but are not limited to:

3.9.1 Interior Health;
3.9.2 The researcher's supervisor;
3.9.3 Health Canada or FDA Inspection reports;
3.9.4 Media reports;
3.9.5 Internet sites for research (Health Canada, OHRP, FDA);
3.9.6 Participant complaints;
3.9.7 Research staff informants;
3.9.8 Site visit reports

3.10 Extensions of Approval Period

3.10.1 There is no grace period extending the conduct of research beyond the expiration date of REB approval. Extensions beyond the expiration date will not be granted.

3.10.2 If the researcher has not submitted the Request for Renewal application form by the expiry date the project will be suspended per policy *RR1200 Suspensions and Terminations of Research Ethics Board Approval*. The researcher, IH sponsor and/or funding sponsor will be notified of the suspension of the project by the REB Chair or designee.

3.10.3 No research related activities may occur after lapse of the REB approval unless the researcher contacts the REB and a determination is made that it is in the best interest of individual participants to continue during the lapse in REB approval.

3.10.4 If a Request for Renewal application form is not received within one month after the lapse, the project will be considered closed and the researcher will be informed in writing by the REB Office. The researcher will be required to submit a new research ethics application for review and approval should he/she wish to proceed with the research project.

3.11 Level of Review

3.11.1 Renewal applications identified as minimal risk will have delegated review prior to approval.

3.11.2 Any minimal risk project due for annual renewal that presents ethical concerns will be forwarded for review at the next scheduled REB meeting.

3.11.3 Renewal applications considered above minimal risk will have full Board review at the next scheduled REB meeting; if there has been little or no change in the ongoing investigation and no increase in level of risk, the renewal will have delegated review.

3.11.4 An annual renewal will be reviewed by full Board when required by the project sponsor, funding agency or regulatory agency.

3.11.5 Annual renewal for a project funded by the US Federal Government or regulated by the US Food and Drug Administration must be reviewed by full Board unless it meets the following criteria:

3.11.5.1 The research is permanently closed to the enrollment of new participants; and

3.11.5.2 All participants have completed all research-related interventions; and

3.11.5.3 The research remains active only for long-term follow up of participants; OR

3.11.5.4 Where no participants have been enrolled since the last review and no additional risks have been identified; or

3.11.5.5 Where the remaining research activities are limited to data analysis.

4.0 PROCEDURES

4.1 Research Ethics Office

4.1.1 Reviews the progress report and determines the level of review. Forwards any queries re: required level of review to the Chair.

4.1.2 Reviews the project file for any outstanding continuing review activities and brings these to the attention of the Chair.

4.1.3 Reviews and approves minimal-risk requests for Renewal on behalf of the REB.

4.1.4 Informs the researcher in writing that the project is considered suspended if a request for renewal application form is not received prior to the expiry of

approval; this means that no research activities are permitted to take place unless and until approval is reinstated. The researcher will be required to submit a new research ethics application for review and approval should he/she wish to continue with the research project.

4.1.5 Maintains a tracking tool on all renewals and reports them to the REB at regular scheduled meetings.

4.1.6 Issues Certificates of Ethical Approval – Renewal to the PI on behalf of the Chair once the renewal request has been approved. Certificates for Approval Renewal are issued for a one year term.

4.2 REB

4.2.1 Reviews above minimal risk projects for annual renewal and identifies any ethical concerns; one primary reviewer will be assigned to present the project renewal to the Board.

4.2.2 Reviews minimal risk projects for annual renewal if there are ethical concerns requiring full Board review.

4.2.3 Makes a recommendation regarding approval of annual renewal.

4.3 REB Chair

4.3.1 Reviews any queries related to the level of review required for renewal.

4.3.2 Reviews any outstanding continuing review activities including safety reports with the renewal application.

4.3.3 If a delegated or full Board review results in recommendations for change, the Chair will communicate the recommendations to the researcher in a Report of Review.

4.3.4 If a research project is suspended, notifies the researcher, sponsor, and the IH Research Navigator in writing.

5.0 REFERENCES

- Canadian Association of Research Ethics Boards and N2 Network of Networks. (2016). Standard Operating Procedure 404.002: *Ongoing REB Review Activities.*
- Canadian Association of Research Ethics Boards and N2 Network of Networks. (2016). Standard Operating Procedure 405.002: *Continuing Review.*
- 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 2014.
- Health Canada, Food and Drug Regulations, Part C, Division 5, *Drugs for Clinical Trials Involving Human Subjects*, (Schedule 1024), June 20, 2001.

RR0500 – RENEWAL OF ETHICAL APPROVAL

- Interior Health. (2018). Research Policy Manual*: RR0400 Continuing Review.*
- 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.
- Island Health Authority. (2013). Research and Capacity Building Policy 509: *Research Ethics Annual Renewals*, version 1.
- UBC Office of Research Ethics. (2013). Standard Operating Procedure 406: *Annual (Interval) Renewals*.
- UBC Office of Research Ethics. (2013). Standard Operating Procedure 406a: *Annual Renewal Processes*.
- US Department of Health and Human Services, Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects (45CFR46).
- US Food and Drug Administration Code of Federal Regulations, Title 21, Volume 1:
  - Part 50, Protection of Human Subjects, (21CFR50).
  - Part 56, Institutional Review Boards, (21CFR56).

**This policy replaces the following policy which is no longer active:
IH REB Policy: *RE0700 Renewals* approved February 27, 2008