RR0500 – RENEWAL OF ETHICAL APPROVAL

1.0 PURPOSE

To provide direction for the annual renewal requirements for ethical approval of research projects involving human participants.

2.0 DEFINITIONS

Term	Definition
Initial Approval	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.
Delegated Review	The level of REB review assigned to minimal risk research projects and to minor changes in approved research projects.
Full Board Review	Review of initial applications or post-approval activities conducted by full membership of the REB.
Renewal	Review and approval of the renewal of ethical approval for a project that continues past the term of initial and subsequent approval(s).
Researcher	The person will overall responsibility for the conduct of the research project at the research site. For clinical trials, the term Qualified Investigator is used for the responsible party at the local site. For other types of research, the term Principal Investigator may be used in place of researcher.

3.0 POLICY

3.1 Periodic review of research projects is necessary to determine whether approval should be continued or withdrawn. The REB will review research involving human participants at intervals appropriate to the degree of risk, but not less than once a year.

3.2 The REB may determine that the research requires continuing review more frequently than once per year, depending upon the level of risk posed to participants.

3.3 The researcher is required to submit an application for renewal of ethical approval of research annually, or at a frequency 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 The researcher is required to submit a Request for Renewal application form or Post Approval Activity 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 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.

3.6 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:

3.6.1 Interior Health;
3.6.2 The researcher's supervisor;
3.6.3 Health Canada or other regulatory agency Inspection reports;
3.6.4 Media reports
3.6.5 Participant complaints;
3.6.6 Research staff;

3.7 Extensions of Approval Period

3.7.1 If the researcher has not submitted the Request for Renewal by the expiry date, the REB will suspend the project per policy *RR1200 Suspensions and Terminations of Research Ethics Board Approval*. The REB Chair or designee will notify the researcher of the suspension of the project.

3.7.2 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.

3.8 Level of Review

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

3.8.2 Any minimal risk project due for annual renewal that presents ethical concerns will be forwarded for full board review.

3.8.3 Level of review for renewal of above-minimal risk projects is determined by the level of risk associated with the Renewal application. If the Renewal is considered above minimal risk, it will have full Board review. 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.

3.8.4 Renewal applications will be reviewed by the full Board when required by the project sponsor, funding agency or regulatory agency.

3.8.5 A Renewal application 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:

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

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

3.8.5.3 The research remains active only for long-term follow up of participants; or

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

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

4.0 PROCEDURES

4.1 Researcher

4.1.1 Submit an Application for Renewal of Ethical Approval or a Renewal Post Approval Activity to the REB with sufficient lead-time to allow the REB to review the application, issue provisos as needed, and for the researcher to respond to provisos prior to the expiry date of the current approval certificate.

4.1.1.1 Renewal applications that qualify for delegated review: submit no later than 4 weeks prior to the expiry date given on the current approval certificate.

4.1.1.2 Renewal applications that require full board review: submit by the application deadline date for the REB meeting that precedes the current expiry date by at least two weeks.

4.1.1.3 Expired studies: submit to the REB Chair. Include an explanation of why the approval was permitted to lapse and provide written assurance that no research has occurred during the period of lapsed approval.

4.1.1.4 For studies not housed on the RISe platform, submit an IH REB application for Renewal of Ethical Approval via email to the REB.

4.2 Research Ethics Board Coordinator

4.2.1 Reviews the renewal application and determines the level of review.

4.2.2 Reviews the project file for any outstanding continuing review activities.

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

4.2.4 Consults the Chair as needed to determine level of review, or for concerns related to the study conduct or outstanding continuing review activities.

4.2.5 Maintains a tracking tool on all renewals and circulates to the REB at regularly scheduled meetings.

4.2.6 Issues Approval Certificates on behalf of the Chair once the renewal request is approved. Approval Certificates are issued for a one-year term unless the renewal period has been determined by the REB to be less than a year.

4.3 REB

4.1.1 Reviews annual renewal applications requiring full board review. One primary reviewer will be assigned to present the project renewal to the Board.

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

4.1.3 Recommends approval of annual renewal or issues provisos as required.

4.4 REB Chair

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

4.3.2 Reviews any outstanding continuing review activities such as safety reports or amendments with the renewal application.

4.3.3 If a delegated or full Board review results in recommendations for change, the Chair will issue provisos to the researcher in writing.

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

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 Association of Research Ethics Boards and N2 Network of Networks. (2019). Standard Operating Procedure 405.003: *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 2018.
- Interior Health. (2019). Research Policy Manual*: RR0400 Continuing Review.*

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- 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 405: *Continuing Review*.

- 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 that is no longer active:
IH REB Policy: *RE0700 Renewals* approved February 27, 2008