**Annual Renewals Guidelines**

**Introduction**

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd edition (TCPS 2, 2018, Article 6.14) requires that Research Ethics Boards (REBs) engage in continuing review of ongoing research activities. Consistent with ethical guidelines, the Saskatchewan Health Authority REB grants ethics approval of new research for a period of one year, after which time researchers must apply for renewed ethics approval on an ongoing basis. Researchers are also required to notify the Research Ethics Board upon completion of a study and must submit a final report. Ethical clearance shall be revoked if a satisfactory progress report is not received.

**When to Submit**

Researchers must complete the form below when:

* Applying for annual reapproval, and
* When closing a study.

Additional Documents Required

**Clinical Trials**
Researchers conducting clinical trials of drugs or manufactured devices must submit the most recent Data Safety Monitoring Board (DSMB) and Periodic Safety Update report (as applicable) along with their application for annual reapproval if these have not been submitted prior to annual renewal. Applications will not be processed without this report. Please note that clinical trials will be charged a reapproval fee of $750 to cover continuing review for the year post renewal.

**Study Closure**
Upon study closure, researchers are requested to submit (1) a final summary report, and (2) a list of all publications and presentations arising from the research. These documents may follow at a later date if they are not yet available.

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**Submission Deadlines**

Submission deadlines for annual reapproval are summarized below. Please refer to the section that applies to your project for more information.

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| **Original review conducted by:** | **Submit:** |
| Delegated review | 10 business days prior to expiry |
| Full board review requiring full board reapproval | See REB meeting deadlines |
| Eligible for delegated reapproval | 10 business days prior to expiry |

**Projects Originally Approved via Delegated Review**

Applications that originally underwent delegated review must be received at least 10 business days prior to the expiry date listed on your most recent approval certificate in order to ensure that approval does not lapse.

**Projects Originally Approved via Full Board Review**

A project originally reviewed by the full board (above minimum risk) may only undergo delegated review for annual reapproval under the following circumstances:

* annual renewals of more than minimal risk research where the remaining research-attributable risk is minimal e.g., the research will no longer involve new interventions to current participants and no additional participants will be enrolled in the study;
* annual renewals of more than minimal risk research in which there has been:
	+ no significant changes to the research,
	+ no increase in risk to (or other ethical implications for) the participants since the most recent review by the full REB, and
	+ the REB Chair has determined that the delegated review process is appropriate. (see TCPS 2, 2018, Article 6.12)

Applications for reapproval for all clinical trials in which enrollment and/or interventions are still ongoing should be submitted with the assumption that full board review will be required.

**What to Expect**
Once your application for annual reapproval is received, it will undergo delegated or full board review, according to the criteria above. When reapproval is granted, you will be issued a Certificate of Reapproval for a period of one year.

**If your application is incomplete**, it will be returned to you for more information prior to reapproval being granted. You may also be requested to make changes to the previously approved consent form or study procedures in order to comply with current ethical guidelines.

**Projects with extended periods of data collection** will undergo a more rigorous review every 5 years in order to ensure compliance with ethical and legislative requirements. Although rare exceptions will be considered (e.g., annual follow-up with the same participants who were recruited earlier in the study), in almost all cases, a new application form will be required. This requirement applies to all types of research, regardless of whether or not direct patient contact is involved, including ongoing prospective databases. The REB will give investigators advance notice if a new application is going to be requested. Reapplications must be complete (e.g., application form, signatures, operational approvals, data collection tools, master list, consent form).