

Guidance on Maximum Annual Renewal Limit

Purpose

This document provides guidance on the five-time renewal maximum allowance for research studies, for a total active period of six years. Projects that have received the maximum number of renewals shall submit a new ethics application to replace the existing application which has exhausted the allowed number of renewals.

Background

An ethics application is a living document that must reflect the current state of the project and modern standards. Annual renewals serve as a mechanism for reviewing the status of on-going research. Over a long period of time, research studies may undergo shifts and changes that result in a study deviating from the original plan, no longer conforming to the approved application. Some examples of changes could stem from preliminary findings of the research study, discoveries from more recent publications, and other factors. Research ethics is also a dynamic field that shifts over time, often due to new and emerging fields, for example in response to new technology, societal values, and historical lessons.

The process of periodic application replacement not only provides an opportunity for researchers to review their project (e.g. change in focus, research plan, overall study design, conflict of interest) and ethical issues surrounding the research, but also for the REB to review and maintain ongoing oversight of the ethical acceptability of all proposed or ongoing research as part of the REB's mandate.

Scope & Application

This guidance applies to all human research with exception to the following*:

- Clinical trials
- Biobanks, databanks, and registries**
- Longitudinal studies involving long-term, direct participant involvement.

* Other exceptions may be allowed upon request

**The REB conducts periodic review of biobanks, databanks and registries on a case-by-case basis and will request new applications if determined that the existing application requires significant revisions to reflect the current guidance, policies, and regulations. Generally, a new application will be requested after 10-15 years, if needed.

For most cases, studies that do not involve direct participant engagement fall under the scope of this guidance. Common examples include chart review studies with waiver of consent and studies using consented data/sample from a registry/biobank.

Process

Researchers are responsible for tracking the renewals and maintaining their ethics applications to ensure that they reflect the current research process and comply with evolving guidance, policies, and regulations. Communication notifying that the application has reached its maximum renewal limit and request for a new application will be indicated at the time of issuance of renewal approval certificate in RISE.

Upon assessment of the project status and timeline, if it is determined that data collection is complete, the ethics application can be closed by submitting a Completion of Study PAA, provided the analysis of data will be in line with the plan outlined in the approved ethics application.

Contact

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Resources and References

- TCPS 2 (2022): https://ethics.gc.ca/eng/policy-politique/tcps2-eptc2_2022.html
- BREB Post Approval Activity (PAA) Instructions: <https://researchethics.ubc.ca/sites/default/files/2024-04/BREB-Post-Approval-Activity.pdf>
- UBC Policy LR9: https://universitycounsel.ubc.ca/files/2022/05/Human-Research-Policy_LR9.pdf