University of Manitoba | Human Research Ethics

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Guidelines for Amending a Protocol vs. Submitting a New Protocol

Overview

The purpose of this document is to provide guidance to researchers and consistency across Research Ethics Boards on the use of amendments to request changes to existing approved protocols vs the requirement for a new REB application

According to the TCPS 2, following initial review and approval of a research study, research ethics review continues throughout the life of the project (Article 2.8). Requests for changes to approved research must be submitted and approved by the REB prior to implementation. However, changes that alter the nature of an approved project may be assessed by the REB as a new research project and require a new ethics application to be submitted (Article 6.16).

Substantial changes to an existing protocol can be difficult to review and there is a higher likelihood of inconsistencies as well as the inclusion of information and documents that are no longer relevant. The REB Chair may require a new protocol to be submitted if the REB determines that it is unable to conduct a thorough ethical review of the protocol.

Amendments to studies should be changes within the scope of the original study, not new studies that are simply related to the original study. If the procedures and data collection described in the original application for ethical review have now been completed, changes that involve new phases, new research questions and/or also entail new procedures, measures, or study populations should be submitted in a new application for ethical review.

When in doubt about whether changes require an amendment or a new protocol, the researcher should seek the opinion of the REB **before submitting any documents**. To do this, email humanethics@umanitoba.ca with the protocol number and an explanation of the changes.

All submissions for REB review are through the Research Administration System (RAS). Proposed amendments are typically reviewed and approved by the Chair. However, at the Chair's discretion, amendments that are submitted may undergo a delegated review or a full Board review. If the REB, after its review, deems an amendment to be substantial, the REB may request that a new protocol be submitted.

Amendments

Only minor changes may be dealt with via the amendment process.

Examples of amendments include:

- administrative changes such as the addition/deletion of a research assistant, co-investigator, and/or student,
- a change in the study funding source, or the addition of a funding source,
- addition of new recruitment tools (e.g., posters),

- expanding a study to multi-jurisdictional research and thus review of the study by another REB,
- amendment to expected participant numbers,
- minor changes to the inclusion and exclusion criteria for participants,
- amendment to data collection measurements such as adding or removing a measurement or test,
- amendment to study dates,
- identifying a conflict of interest that has arisen and how it will be mitigated, or
- changes/additions to dissemination plans.

Amendments must include all revised information letters, consent forms, recruitment tools, data collection tools, etc. Proposed changes to the approved study documents must be highlighted or indicated using track changes to facilitate REB review.

Changes Requiring a New Protocol

In cases where the researcher is undertaking an initiative that involves substantial changes to the original protocol, a new application is normally required. As a general rule, if several sections of the application are being revised, a new application is likely needed. If you intend to analyze data for a purpose outside of what was originally approved in the application, a new ethics protocol is required.

Examples of changes requiring a new protocol include:

- altering the research purpose,
- addressing a different research question,
- proposing new phases,
- extending the study to include a new participant population,
- changing the data collection tools (rather than simply adding/removing a tool),
- changing data collection from anonymous data to identifiable data,
- changes to the study that increase the level of risk to participants,
- adding participants who may be considered vulnerable in the context of the research,
- adding a deception element, or
- making changes to an older study which no longer complies with current TCPS2 expectations, current University policies, and or/ other regulatory or legislative requirements.