

Guideline #: 002 – 15-16
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**Title: Project Amendment vs New Protocol Submission**

*Question:* What constitutes an amendment and what should be submitted as a new project?

*Purpose:* To provide guidance to Principal Investigators (PIs) and consistency across time with respect to the use of the *Request for Amendment/Addition to a Project Form* versus the requirement for a full REB submission to document changes to existing approved protocols. This document is intended to provide guidance rather than to present a set of rules.

Amendments must be minor in nature and not be additional interventions/phases which may alter the study's original purpose. Revised information letters, consent forms, recruitment tools, data collection tools etc., must be included with all requests for amendment with the proposed revisions highlighted for review.

All planned changes to a study protocol must receive approval prior to implementation and must be submitted to the REB review through the Romeo Researcher Portal. Proposed amendments are normally reviewed and approved by the Chair. However, at the Chair's discretion, the Chair can request a delegated committee review, a full Board review, or a new protocol be submitted.

If the REB, after its review of an amendment, deems an amendment to be major, the REB can request a new protocol be submitted.

Examples of amendments are as follows:

- 1) Administrative changes such as the addition/deletion of a co-investigator or student.
- 2) A change in the study funding source, or the addition of a funding source.
- 3) Addition of new recruitment tools i.e. posters.
- 4) A change to where and with whom the research will be conducted with i.e. from internally (Lakehead University) to general population. The new population must not be considered vulnerable.
- 5) Expanding a study to multi-jurisdictional research and thus review of the study by another REB.
- 6) Amendment to expected enrollment numbers.
- 7) Amendment to method of data collection that doesn't change the data from anonymous to identifiable
- 8) An identified conflict of interest and how this will be avoided/mitigated.
- 9) Change/addition to dissemination plan.

Examples of protocol changes that require a new REB submission:

- 1) Changes that shift the study from minimal risk to greater than minimal risk.
- 2) Addition (or discovery) of your participant pool being a vulnerable population.
- 3) New method of data collection that changes the data from anonymous to identifiable.
- 4) A change in the study's purpose.
- 5) An additional phase or new stage of the research which involves any of the following: new participant pool, new methodologies, new recruitment, new data collection methods.
- 6) Addition of deception.

*In all cases, appropriate justification for the changes/additions needs to be provided.*