Western Research

Western University
Room 5150 Support Services Building, 1393 Western Road
London, Ontario, Canada, N6G 1G9
Tel: 519-661-2161
ethics@uwo.ca

Guidance Document	When to Submit an Amendment vs. New Application
Effective Review	Delegated & Full Board (NMREB&HSREB)
Version Date	January 6, 2026

OVERVIEW

This guidance document outlines when researchers should submit an Amendment form for their research project and when a new application is required. Typically, amendments are submitted any time there is a change to the original protocol. If the proposed changes are substantive in scope or nature, a new application is required. For the purposes of this document, "substantive changes" refers to changes that meaningfully modify what the study is trying to answer or how it is being answered.

SHOULD I SUBMIT AN AMENDMENT?

According to the Tri-Council Policy Statement (TCPS2, 2022), Article 6.16, an amendment must be submitted when the researcher is changing any part of the study at any stage of the research (e.g., consent forms, procedures, study team members, study title, funding, any approved study documents, etc.). The researcher must submit the amendment and must receive approval prior to implementing the proposed change(s). An amendment may be reviewed through a Delegated Review or a Full Board review based on the level of risk and the nature of the proposed changes.

Generally, if the change does not substantially alter the specific aims or the design of the study, an amendment is appropriate. Such changes include, but are not limited to:

- Changing the sample size (HSREB only)
- Broadening or narrowing the inclusion or exclusion criteria
- Adding or updating the recruitment methods and materials
- Changing the Letters of Information, consent or assent forms and/or consent procedures
- Changing approved data collection tools, such as survey instruments, interview guides, debriefing letters, etc.
- Adding or changing study team members
- Identifying a conflict of interest that has arisen and how it will be mitigated
- A change in the study funding source, or the addition of a funding source
- Procedural changes that are limited in scope such as changing the location of study activities or estimated time commitments/frequency of visits.

Amendments must include all revised information letters, consent forms, recruitment tools, data collection tools, etc. Proposed changes to the approved study documents must be tracked using MS Word "track changes". Both tracked and clean untracked versions must be submitted for review.

DO MY CHANGES WARRANT A NEW APPLICATION?

Proposed changes that substantially alter the specific objectives or design of the approved project may be considered a new research project and therefore require that a new REB application be submitted (TCPS2, 2022, Article 6.16).

Examples of protocol changes that may be considered a new research project, and require a new REB submission include, but are not limited to:

- Changing the objectives of the research or including new objectives outside the original research question as defined in the initial REB application.
- Substantial changes to the overall design of the research project and described study activities
- Changes that shift the study from minimal risk to greater than minimal risk.
- Addition of participants who may be considered vulnerable in the context of the research.
- An additional phase or new stage of the research that was not described in the initial REB approved application.
- Open label extensions not included in the approved initial application.
- The addition of deception to the research protocol.
- Making changes to an older study that no longer complies with TCPS2 requirements, current University policies, and/or other regulatory or legislative requirements.
- The addition of secondary use of data that are *not* anonymous.

Qualitative Research Involving Emergent Design:

Emergent Design refers to the process of data collection and analysis evolving over the course of a research project in response to findings from earlier stages.

This approach is useful when elements of data collection are difficult to anticipate or fully identify before the research begins. Stages of an emergent design study can be submitted as separate study modifications to an existing REB application, provided that subsequent stages continue to address the same research question and do not significantly alter the study design.

In the initial application, researchers should specify for which phases or parts of the study they are currently seeking REB approval, and which will be conducted later, for which they will submit an amendment. Researchers are encouraged to provide as much information as possible about the various phases of emergent design and to consider the ethical implications of any changes to data collection procedures, especially where changes in the level of risk may affect participant welfare. Approval from the REB must be obtained before implementing changes to the study.

When doubt exists about whether changes require an amendment or a new protocol, the researcher should seek the opinion of the OHRE before submitting any documents. To do this, use the correspondence option within your WREM file and include an explanation of the changes, contact the Ethics Officer on your project, or use ethics@uwo.ca.