

REB Guideline: Minor and Substantive Changes to Research with REB Clearance

Current Status: Approved and Posted

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As a condition of continued ethics clearance, researchers must conduct their research according to the details provided in their originally approved application. The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2, 2014)* Article 6.16 states that it is a researcher's responsibility to submit requests for substantive changes to their REB approved study prior to implementing those changes. If there is any doubt as to whether a change requires REB review, the researcher should contact the Office of Research Ethics (ORE; reb@brocku.ca) to confirm their individual case.

What constitutes a change?

Some research, by nature, evolves over time and therefore adjustments to the research are expected. In general, it isn't the magnitude of the change that determines whether it is or is not "substantive," but the ethical implications associated with the proposed change and the extent to which it elevates risk. The REB must receive and review any proposed changes that might affect the rights, safety, and well-being of research participants (TCPS2 Article 6.16).

For more details on what constitutes research personnel, please consult [REB Guideline: Definition of a Research Team](#).

1. Substantive changes:

Substantive changes are modifications to research that "affect participants at any stage of the process including, but not limited to, changes in the consent form, changes in the tasks or interventions, or changes to measures to protect privacy and confidentiality." (TCPS2, 2014, Article 6.16). This could also include changes in participant recruitment procedures, participant demographics, addition of a research topic, or changes in the handling of research data, including the addition of new personnel or research team members. Substantive changes must not be implemented until REB clearance for the change has been secured through a Request for Change form unless immediate changes are required to protect participant safety (Article 6.16). Note that a maximum of five (5) substantive changes will normally be allowed before a resubmission of the application is required. For more details on this process, please consult [REB Standard: Maximum Number of Annual Renewals and Substantive Changes](#).

2. Minor changes:

Minor changes are adjustments or refinements to research that do not alter the level or nature of risk or affect participant safety, comfort, privacy, or confidentiality. Minor changes should be reported in a timely manner as an email update to the ORE and must, at minimum, be summarized in annual status reports. Examples of minor changes include but are not limited to slight increases or decreases of testing time, wording adjustment on a research instrument or interview guide to provide clarity without changing meaning, removal of some or all items from a research instrument or interview guide, switching to an updated version of a published instrument, or switching to another research instrument addressing conceptually similar subject matter. Changes to personnel or the research team (including but not limited to research/laboratory staff, project managers, or research assistants where they will be responsible for recruiting or interacting with human participants or have access to data in an identifiable form) are considered minor if the changes are consistent with the consent form as cleared by the REB and provided to research participants, and do not alter the level or nature of risk or affect participants' safety, comfort, privacy, or confidentiality. However, should changes to personnel or the research team involve the addition of

any Brock graduate students, their TCPS2 CORE tutorial certificate must be submitted to the ORE, prior to engagement with human participants or data (per Brock University policy).

If a researcher is unclear as to whether a change is minor or substantive, they are advised to contact the ORE.

Review process for proposed changes:

- At Brock, most modification requests are delegated, and decisions are made by the REB Chair and the ORE. However, depending on the level of risk introduced by the request, such requests may require the greater scrutiny of a full board review.
- If a proposed change substantially affects the participants' safety, comfort, privacy, or confidentiality, or substantially alters the nature of the approved research, it may be assessed as a new research project and researchers may be required to submit a new application.