



Amendment or New Ethics Application Guidelines

After a research project has received ethics clearance, **any** proposed changes to the research must be reviewed by the Research Ethics Board (REB) per [TCPS 2 Article 6.16](#):

- In the conduct of their approved research, researchers must submit requests for any changes to their original ethics application via submission of an amendment via the [ROMEIO Researcher Portal](#).
- After the REB provides an assessment of a request, requests for changes to ethically review research may receive delegated or full REB review depending on the level of risk to participants that the change(s) represents.
- Proposed changes to the research that affect participants at any stage of the process including, but not limited to, changes to the consent form, changes to the tasks or interventions involved in the research, changes to the level of risk, or changes to measures to protect privacy and confidentiality must be submitted to the REB in a timely manner.
- Any substantive change to the research cannot be implemented without documented ethics clearance by the REB, except when necessary to eliminate an immediate risk(s) to the participants.

If the proposed change substantially alters the nature of the ethically cleared research, a new ethics application may be required.

Requests for Changes to Ethically Cleared Research:

- It is not the magnitude of the change that dictates if a new ethics review is required, but rather the ethical implications and risk associated with the proposed change.
- When circumstances arise that may necessitate change in long-term research, such as new knowledge, equipment, assessments, interventions, study instruments, or new or revised applicable policies and laws that may develop over the lifetime of a research project, these may require a new submission, particularly when changes impact the initial research scope and/or primary/secondary objectives of the study.
- **If you are unsure whether your change will require an Amendment or a New Application, contact the [RIA Ethics & Education team](#).**

Sub-Studies:

- Generally, a sub-study asks separate research questions from the parent protocol, although it may contribute to its objectives. The sub-study may include, but is not limited to, the use of a subset of study participants, data and/or specimens.
- In general, sub-studies methodologies deviate significantly from the parent study. They are not accurately captured in the initial ethics application (e.g., changes in how information is collected, stored, used, disseminated).
- **The IWK REB requires a new and independent submission to the REB for all sub-studies.**

Emergent Design Studies:

- Some studies are designed to be responsive to what is being learned during the conduct of the research. In these cases, it may not be possible to communicate the specific research methods/assessment tools at the outset of the study (e.g., Patient engagement research (SPOR), community engagement in research). It often involves using a variety of data collection strategies (e.g., interviews, surveys, focus groups), and only as common themes emerge can further methodological developments occur.
- The general details of the emergent design study must be included in the initial ethics application, as well as a statement that amendments will be submitted as methods/assessment/measurement tools emerge.
- **Any significant changes to the initial scope of the project and/or the use methods for information as it relates to the collection sharing/storing and dissemination, as not previously suggested in the initial application, may require a new ethics submission.**