Conjoint Faculties Research Ethics Board (CFREB)
Research Services, University of Calgary
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Modifications vs. New Applications

Requests for changes to approved research

Following initial review and approval, research ethics review continues throughout the life the project (Article 2.8 of the TCPS2). Requests for changes to approved research need to be submitted to the REB prior to implementation. Proposed changes that substantially alter the specific aims or design of the approved project may be assessed as a new research project, and require a new ethics application be submitted (Article 6.16). In general, it is not the scope of the change that dictates the ethics review process but rather the ethical implications and risks associated with the proposed change.

Generally, if a Principal Investigator (PI) is making a minor or editorial change to a currently approved study that does not substantially change the specific aims or design of the study, a request for a modification is appropriate. This might include:

- Increasing the number of participants,
- Broadening or narrowing inclusion criteria,
- Broadening recruitment efforts,
- Changing approved data collection instruments, such as the addition of measurement tools, questionnaires or tests,
- Editorial changes to consent forms, data collection instruments, or recruitment materials,
- Adding approval certificates or letters of support from organizations where approval has been granted.

In cases where a PI is undertaking an initiative that addresses a different research question(s) or the "modification" is starting from the beginning (e.g., new research team, new funding, new recruitment efforts, new method of data collection, new or increased risks, revised analysis plan, etc.), a new application is likely warranted. Usually, if most sections of the application are revised, or the research question is changing, a new application is probably needed. The scope of proposed changes is assessed by the Chair and Research Ethics Analysts (REA) as a part of the modification review process. If the Board determines that the scope of the proposed changes substantially alters the specific aims or study design, the study team may be advised that a new application is required.

Emergent Design Research:

Emergent Design refers to:
"data collection and analysis that can evolve over the course of a research project in response to what is learned in earlier parts of the study" (Article 10.5).

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This can be used when elements of data collection may be difficult to anticipate or fully identify portions of the research prior to its implementation.

Stages of an emergent design study can be submitted as separate study modifications to an existing certification in IRISS as long as subsequent stages are still answering the same research question and do not significantly alter the study design.

In the initial application, you can note what phases or parts of the study you will be seeking ethics approval for now and which phases or parts will be conducted at a later date, for which you will submit a modification. We ask that researchers provide as much information as possible about the various phases of the emergent design and consider the ethical implications of any changes to data collection procedures, where changes in the level of risk may affect the welfare of participants. Researchers need to seek approval from the REB prior to implementing these changes into the study.