

Protocol Amendments / Modifications vs. New Applications

Consistent with [TCPS 2 Article 2.1](#), the following types of research require ethics review and approval by an REB before the research commences:

- A. Research involving living human participants (either directly or indirectly through collection of stored data).
- B. Research involving human biological materials (tissues, organs, blood, plasma, serum, DNA, RNA, proteins, cells, skin, hair, mail clippings, urine, saliva and other bodily fluids), as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals

Research is defined as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation. This includes pilot studies ([Article 6.11](#)).

The approach to review requires that REBs examine the potential benefits as well as likelihood and magnitude of risks. REBs take a proportionate approach to review; the level of scrutiny is tailored to the level of risk presented by the research project. Projects that are considered minimal risk (i.e., where the probability and magnitude of harms implied by participation in the research are no greater than those encountered by participants in those aspects of their everyday life) are eligible for delegated review. Those that are considered above this minimum risk threshold undergo review by the full REB.

Where in doubt about the applicability of review to a particular research project, the researcher should seek the opinion of the REB.

Requests for changes to approved research

Following initial review and approval, research ethics review continues throughout the life the project ([Article 2.8](#)). Requests for changes to approved research need to be submitted to the REB prior to implementation. Changes that substantially alter the nature of an approved project may be assessed as a new research project and require a new ethics application be submitted ([Article 6.16](#)).

Ethics review is intended to be undertaken on a study-by-study basis and does not extend to research programs. The addition of "sub-studies" to currently approved studies is not permissible. This does not apply where sub-studies are outlined as part of a Sponsor-initiated protocol (e.g., genetics sub studies, pharmacokinetic sub studies)

Application:

Generally, if a Principal Investigator (PI) is making a minor 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:

- increase/decrease in enrolment,
- broadening/narrowing inclusion criteria,
- changing measurements such as the addition of a measurement or test,
- a change in drug dose, or
- a change in visit schedule

In cases where a PI is undertaking an initiative that addresses a different research question and the “modification” is starting from the beginning (e.g., new research team, new funding, new recruitment/data collection, revised analysis), a new application is warranted. As a rule of thumb, if most sections of the application are being revised, a new application is probably needed.

Sometimes these situations are ambiguous and in such cases, the CHREB welcomes consultation.