**CONJOINT HEALTH RESEARCH ETHICS BOARD (CHREB)**
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# Protocol Amendments / Modifications vs. New Applications

## General Guidance – The Need for REB Review

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, nail 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 harm 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.

## Modifications to an Approved Study:

Following initial review and approval, research ethics review continues throughout the life the project (Article 2.8). Modifications to an approved research study must be submitted to the REB prior to implementation within the IRISS platform. Modifications should be within the scope of the original study, and not new studies that are simply related or rely on the original study. Below, guidance is provided on when a new application or modification applies. If the main protocol includes a nested sub-study, the same considerations apply.

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**When to submit a modification:**

Generally, if a Principal Investigator (PI) is making any change to an 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, but is not limited to:

- changes in participant-facing materials (consent form, recruitment materials, etc.)
- increase/decrease in the sample size
- broadening/narrowing inclusion criteria,
- changes to measurements such as:
    - the addition or removal of a measurement or test
    - revisions to data collection instruments (i.e., interview guides)
- changes in the dose of an interventional arm
- changes in the visit schedule
- changes in data storage or data management procedures

If the study is a Health Canada monitored clinical trial, submission of Clinical Trial Application - Amendments (CTA-As) or revised Investigational Testing Authorization (ITA) to Health Canada may also be required. The study team can consult with the Clinical Trials Office for inquiries related to this.

**When to submit a new application:**

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).

It is not the magnitude of the changes that determine this, but rather the ethical implications and risks of the proposed change. This might include, but is not limited to:

- a different research question or revised scope of the study
- new research study, funding, recruitment plan, and data collection procedures
- new group of participants required to answer the revised research question

As a rule of thumb, if most sections of the application require revision, a new application is most likely needed. Where the research team is unsure if the proposed changes should be submitted as a modification or a new application, the **CHREB welcomes consultation**.

**Research studies utilizing previously collected health information under the *Alberta Health Information Act*:**

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The *Alberta Health Information Act* (HIA) lays out the responsibilities for the disclosure and use of health information in Alberta for research purposes. Research teams are encouraged to review the guidance from the Office of the Information and Privacy Commissioner.

If a research study involves the use or disclosure of health information as defined by the HIA, the REB is obligated to review the study per Part 5, Div. 3, s. 50 of the legislation.

Data custodians also have obligations outlined under the Act. See the general guidance on obtaining operational approvals from AHS. A research agreement with the data custodian (i.e. AHS) is required for use of health information Part 5, Div. 3, s. 54. As of April 2023, UCalgary research teams can submit an AHS Resource & Facilities Request within the IRISS system directly. More details about this can be found here.

Health information released under an existing REB certificate and research agreement remains under the ownership of the custodian and cannot be 're-used' to address new research questions. When a modification or a new application is submitted and proposed to 're-use' already collected health information under a research agreement, the REB and data custodian must still apply the considerations under the HIA. A new waiver of consent and/or revised research agreement with the data custodian may be warranted. This ensures that the disclosure and use of health information is compliant with the HIA.