Policy Supporting Document:	E-3.2.1
Policy Holder:	President

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Researchers and REB members must disclose re

approach to ethics review thus starts with an assessment, primarily from the viewpoint of the potential subjects, of the character, magnitude and probability of potential harms inherent in the research. The concept of minimum risk provides a foundation for proportionate review.

In practice, proportionate review implies different levels of REB review for different research proposals. The REB Chair will vet all applications to determine whether full or expedited review is required. The three levels are full REB review; expedited REB review by the REB Chair; and departmental-level review of student projects within Camosun course requirements carried out by Departmental Chairs.

1. Full REB Review

Full review by an REB is the default requirement for all research involving human subjects.

2. Expedited REB

Research that is expected to involve minimal risk may be approved by the REB chair or chairõs designate.

All expedited reviews approved by the REB chair must be reported back to the full REB, permitting the REB to maintain surveillance over the decisions made on its behalf. Regardless of the review strategy, the REB is responsible for the ethics of all research involving human subjects that is carried out within the College.

Some examples of categories for which an expedited REB revie

2. Involvement of Researchers in the Decision-making Process

Whenever possible, the formal REB decision on whether to allow the research will be preceded by discussion with researchers. Such discussions are often very helpful to both the REB and the researcher and, moreover, are integral to fulfilling the REBôs educational mandate. Especially in complex research proposals, the REB should accommodate reasonable requests from researchers to participate in extensive discussions about their proposals.

a) Discussions involving the researcher may result in a deferral of the REB's decision until the researcher has considered the discussions and possibly modified the proposal.

b) When an REB is considering a negative decision, it will provide the researcher with all the reasons for doing so and give the researcher an opportunity to reply before making a final decision.

c) Researchers may not be present when the REB is making its formal decision.

3. Disagreement

a) In the event that a minority within the REB membership considers a research project unethical, even though it is acceptable to a majority of members, an effort will be made to reach consensus. Consultation with the researcher, external advice, and/or further reflection by the REB will be sought as appropriate.

b) If disagreement persists among the REB, a decision of the majority rules. The Chair will monitor the REB's decisions for consistency, ensure that these decisions are recorded properly, and ensure that researchers are given written communication of the REB's decisions (with reasons for negative decisions) as soon as possible.

c) The Chair will inform the Vice President responsible for research of dissenting votes and the reasons for them.

4. Scholarly (Peer) Review

The purpose of scholarly (peer) review is to elucidate whether the research project (1) adheres to established, high scholarly standards stipulated by the relevant discipline; (2) is capable of addressing the questions being asked in the research; and (3) will further the understanding of the phenomenon or issue in question.

a) It is the REBôs responsibility to ensure that an appropriate form of scholarly review has been completed for each research project that requires full review.

b) It is the researcherôs responsibility to make arrangements for the undertaking of the review.

c) If

nature of the findings. The safeguard for those in the public arena is through public debate and discourse and, in extremis, through action in the courts for libel.

b)

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Ongoing research is subject to continuing ethics review. The rigour of the continuing review will be in accordance with a proportionate approach to ethics assessment.

The REB is responsible to ensure that continuing review of ongoing research takes place to its satisfaction. Review will take place at a minimum of once a year. The REB must ensure it has

Endnotes

[1] "At the start of the trial, there must be a state of clinical equipoise regarding the merits of the regimens to be tested, and the trial must be designed in such a way as to make it reasonable to expect that, if it is successfully conducted, clinical equipoise will be distributed." Freedman, B., "Equipoise and the Ethics of Clinical Research." *New England Journal of Medicine*. 1987, 317.3: 141