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| | Vice President,<br>Academic and Provost | 2008 Nov |
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Research involving Human Participants must be conducted in a manner that is sensitive to the inherent worth of all human beings. Respect for human dignity is expressed through the three core ethical principles of justice, respect for persons and concern for welfare. Douglas College (the College) requires and supports the highest ethical standards in conducting Research involving Human Participants to ensure their rights are respected and protected.

The purpose of this policy is to delineate the ethics protocols that Researchers at or associated with the College must follow to ensure that their Research protects Human Participants; and to ensure that Researchers are aware that Research involving Human Participants may also be governed by federal, provincial and local laws, and by the standards and obligations of particular disciplines. It is the Researcher's responsibility to know and follow these additional requirements.

This policy applies to all Douglas College employees, Students and other Research personnel associated with the College, including emeritus faculty members where applicable.

Research that involves the cooperation of Researchers, institutions, organizations and/or Indigenous or other Communities, each bringing distinct expertise to a project, and that is ceTw -135BctEnJ-0.0148 (e)10.1eeTw -1o(ppl-5.27(d)2.9be uon8.8 (n)41(i)-0Ethical Conduct for Research Involving Humans Policy

Any facilities, equipment or financial aid provided or administered by the College, including without limitation any facilities, physical structures, classrooms, Research laboratories, equipment, technical facilities, personnel and services of the College, including the administration of funds received by the College in the form of grants, contracts or any other support provided by the College, affiliated agencies, partners or external sponsors.

A group of people with a shared identity or interest that has the capacity to act or express itself as a collective; the shared identity may be territorial, organizational or interest-based.

A process that establishes an interaction between a Researcher (or Research team) and a Community with regard to a Research project, and that signifies the intent of forming a collaborative relationship between Researchers and Communities.

1. Primary institutional responsibility for Research involving Human Participants at the College is vested in the Douglas College Research Ethics Board (REB) and with the individual Researchers.

2. The REB operates in compliance with the *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans,* 2nd edition (TCPS2), endorsed by the Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada and the Social Sciences and Humanities Research Council of Canada. As per Article 2.1 (a) and Article 6.11 of the TCPS2, all Research that involves Human Participants requires review and approval by the REB before the Research is started, except as stipulated below (see section A.1.3).

3. The College requires all Researchers to adhere to this policy and its related procedures and guidelines.

b. All members will be appointed by Senior Management, on the recommendation of the REB Chair. Senior Management will provide staff support and necessary resources for the REB.

c. Working through Faculty Education Committees (FECs) and with the Deans, the REB will identify suitable candidates with the required skills and expertise to serve on the REB. The REB may itself appoint up to two (2) additional voting members to two-year terms, with expertise to balance the composition of the REB.

d. The REB may from time to time also call on specialists with subject matter expertise to advise on particular proposals that require such additional expertise.

e. Appointment to the REB is for a two-year term, with terms of members overlapping. The appointment is renewable to a maximum of three (3) terms.

f. The REB will elect a Chairperson every two (2) years from among its membership. The position is renewable.

g. The Chair may remove members if this action is deemed necessary according to the consensus of the REB. This step should only be contemplated in the face of serious failure to meet the obligations of service to the REB, or of a breach of this policy.

h. Prior to serving, all members of the REB will attend a workshop or orientation session, to ensure that they have an understanding of the principles and practices of ethical review. The workshop requirement may be substituted by the online tutorial accessed at https://tcps2core.ca/welcome or a similar tutorial approved by the REB.

(Article 2.7; Article 3.6)

1. As part of Research ethics review, the REB shall review the ethical implications of the methods and design of the Research. The extent of the review for scholarly standards that is required for biomedical Research that does not involve more than minimal risk will vary according to the Research being carried out.

2. Research in the humanities and the social sciences which poses, at most, minimal risks shall not normally be required by the REB to be peer reviewed.

3. REBs should be aware that some Research, involving critical assessments of public, political or corporate institutions and associated public figures, for example, may be legitimately critical and/or opposed to the welfare of those individuals in a position of power, and may cause them some harm. There may be a compelling public interest in this Research. Therefore, it should not be blocked through the use of risk-benefit analysis. Such Research should be carried out according to the professional standards of the relevant discipline(s) or field(s) of Research, and Articles 3.2, 3.12, 9.7, and 10.2 of the TCPS may apply. (Article 3.6 application)

4. Researchers have a role to play in demonstrating to their REB whether, when and how appropriate scholarly review has been or will be undertaken for their Research. (Article 2.7)

REBs may request that the Researcher provide them with the full documentation of

i.

Where a proposal poses more than minimal risk (as defined by the Tri-Council Guidelines, Article 2.B), the REB will assess the harms and benefits of the proposed Research project, and will ensure that the Research procedures and materials conform to established ethical standards.

ii. (Results of these reviews will be reported back to the full REB in a timely manner)

Where a proposal poses only minimal risk or has been approved elsewhere by a Tri-Council policy-compliant REB, the Chair (or designate) of the REB will review the proposal and its conformity to established Research ethics standards and practices. Researchers may request a delegated review when submitting their proposal.

iii. (Results of these reviews will be reported back to the full REB in a timely manner.)

Research conducted by Students under the supervision of an instructor as part of an approved course outline does not need approval from the REB. Instead, the appropriate FEC will review the ethics of the generic Research activities as part of its curricular review processes. The Research activity must be listed in the course Curriculum Guidelines and must refer to the requirements laid out in this policy. Faculty supervising Students will ensure compliance with this policy. Copies of appropriate generic consent forms and Research ethics guidelines approved by the REB should be provided by the instructor to the Students. In situations where Student Research activities will depart from using these forms, the faculty member should refer the matter to the REB for approval. Where Students are carrying out Research that is part of a faculty member's own Research program, this proposal must be reviewed by the REB as in the Full Review procedure (D1.a.i) or the Delegated Review procedure (D.1.a.ii) outlined above.

iv.

a. Ongoing Research shall be subject to continuing ethics review. The rigour of the review will be in accordance with a proportionate approach to ethics assessment. (Article 6.14)
b. The REB shall determine the level at which continuing ethics review occurs in accordance with a proportionate approach to ethics review. (Article 6.14)
c. Normally, continuing review should consist of at least the submission of a succinct annual status report to the REB. For minimal-risk Research projects of less than a year's duration, an end-of-study report may suffice. (Article 6.14)
d. Beyond scrutinizing reports, the REB will not normally carry out the continuing ethics review, except in specific cases where the REB believes that it is best suited to intervene. For Research posing significant risks, the REB should receive reports on the progress of the Research project at intervals to be pre-determined. These reports should include an assessment of how closely the Researcher and the Research team have complied with the ethical safeguards initially proposed.

authorized representatives of the College, Researchers and funding agencies. (Article 6.17)

b. The REB will prepare and maintain adequate documentation of REB activities, including the following:

   i. Copies of all Research proposals reviewed, certificates of approval, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports by Researchers and reports of injuries to Participants;

   ii. Records of continuing review activities;

   iii. Copies of all correspondence between the REB and the Researchers;

   iv. A list of REB members; and

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6. Reconsideration

    a. Researchers have the right to request, and the REB has the obligation to provide, reconsideration of decisions affecting a

such exists, with the legal responsibility and equivalent ethical and procedural safeguards in the country or jurisdiction where the Research is to be done. (Article 8.3)

b. The College is responsible for the ethical conduct of Research undertaken by its faculty, staff or Students regardless of the location where the Research is.

1. Research governed by this policy may begin only if (1) prospective Participants, or authorized third parties, have been given the opportunity to give free and informed consent about participation, and (2) their free and informed consent has been given and is maintained throughout their participation in the Research. (Article 3.3; Article 3.5)
2. Evidence of free and informed consent by Participant or authorized third party should ordinarily be obtained in writing. Where written consent is culturally unacceptable, or where there are good reasons for not recording consent in writing, the procedures used to seek free and informed consent shall be documented. (Article 3.12)
3. (Article 3.7) The REB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided that the REB finds and documents that:
   a. The Research involves no more than minimal risk to the Participants;
   b. The waiver or alteration is unlikely to adversely affect the rights and welfare of the Participants;
   c. The Research could not practicably be carried out without the waiver or alteration;
   d. Whenever possible and appropriate, the Participants will be provided with additional pertinent information after participation; and
   e. The waivered or altered consent does not involve a therapeutic intervention.
4. In studies including randomization and blinding in clinical trials, neither the Research Participants nor those responsible for their care know which treatment the Participants are receiving before the project commences. Such Research is not regarded as a waiver of

demonstration or public meetings, should not require REB review, since it can be expected the Participants are seeking public visibility. (Article 10.3, Application)

1.

Researchers shall provide, to prospective Participants or authorized third parties, full and frank disclosure of all information relevant to free and informed consent. (Article 3.2) In addition, consent shall be an ongoing process. (Article 3.3) Researchers have an ongoing duty to provide Participants with all information relevant to their ongoing consent to participate in the Research. Throughout the free and informed consent process, the Researcher must ensure that prospective Participants are given adequate opportunities to discuss and contemplate their participation. Subject to the exception in Article 3.7, at the commencement of any process of consent, Researchers or their qualified representatives shall provide prospective Participants with the information set out in the following list, as appropriate to the particular Research project. Not all of the listed elements are required for all Research, and additional information may be required in some types of Research or in some circumstances. The information generally required for informed consent includes the following:

a. Information that the individual is being invited to participate in a Research project;
b. A clear, easy to understand statement of the Research purpose, the identity of the Researcher, the identity of the funder or sponsor, the expected duration and nature of participation, a description of Research procedures, and an explanation of the responsibilities of the Participant;
c. A clear, easy to understand description of all reasonably foreseeable risks and potential benefits that may arise from Research participation, both to the Participants and in general, that may arise from Research participation;
d. An assurance that prospective Participants are under no obligation to participate; are free to withdraw at any time without prejudice to pre-existing entitlements; will be given, in a timely manner throughout the course of the Research project information that is relevant to their decision to continue or withdraw from participation; and will be given information about their right to request withdrawal of their data or human biological materials, including any limitations on that withdrawal;
e. Information concerning the possibility of commercialization of Research findings, and the presence of any real, potential, or perceived COI on the part of Researchers, their institutions or the Research sponsors;
f. The measures to be undertaken for dissemination of Research results and whether Participants will be identified directly or indirectly;
g. The identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the Research to Participants;
h.

individual concerning participation. The potential Participant's dissent will preclude his or her participation. (Article 3.10)

4. The age of majority in British Columbia is 19 years of age, and parental consent is required for Participants younger than 19. Consistent with Section 3, above, an opportunity must be given to the individual to refuse to participate or to withdraw at any time. A copy of what is written or said to the individual must be included for review by the REB. The REB considers minors attending post-secondary education, who are 17 to 18 years of age, to be emancipated adults for the purposes of minimal risk Research. Parent or guardian consent will be required only if the Research study is deemed non-minimal risk or represents an invasion of the family's right to privacy. In either case, justification must be provided in the application for the ethics review. The REB may make an exception to these requirements on a case-by-case basis, but the Investigator must provide adequate justification in the

Researchers and REB members shall disclose actual, perceived or potential

- BC *College and Institute Act* [RSBC 1996], c. 52
- Canadian Institutes of Health Research
- Natural Sciences and Engineering Research Council of Canada
- Social Sciences and Humanities Research Council of Canada
- *Tri Council Policy Statement on Ethical Conduct for Research Involving Humans* (TCPS2)

- Current *Collective Agreement between Douglas College and the BC General Employees' Union (BCGEU)*

- Current *Collective Agreement between Douglas College and Douglas College Faculty Association (DCFA)*