DOUGLASCOLLEGE

A02.10.05 Ethical Conduct for Research Involving Humans

Effective Date: November 18, 2008	**New:**
Replaced: Ethical Conduct for Research Involving Humans	**Revision**: November 19, 2012

Policy Statement

Article 2.1 (a); Article 6.11
All research that involves human participants requires review and approval by the Research Ethics Board (REB) in accordance with this Policy Statement, before the research is started, except as stipulated below in section A.1.3. The College expects all researchers to adhere to this policy and its related procedures and guidelines.

NOTE:
This policy complies with the 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. **NOTE: Each excerpt from/reference to this Policy Statement used in this document is referenced by its Tri-Council Policy Statement Article number.**

Purpose

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 respect for persons, concern for welfare, and justice. 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. Researchers at or associated with the College are required to follow research ethics protocols to ensure their research protects human participants.

Primary institutional responsibility for research involving human participants at the College is vested in the Douglas College REB and with the individual researchers. This policy applies to all College employees, students and other research personnel associated with the College, including emeritus instructors where applicable. Researchers must be 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.

Related Polices

A02.10.06 Academic Freedom

A02.10.03 Commercialization of Intellectual Property

A02.01.01 Conflict of Interest

A08.01.01 College Use of Copyrighted Works

A02.10.04 Integrity in Research and Scholarship

A16.01.04 Records Management and Retention Policy

A02.10.02 Research and Scholarly Activity

Definitions

Research:
An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.

Researcher:
Any person associated with the College who undertakes to conduct research. This includes employees and students as well as persons from the community who are associated with a College-generated research project. The Principal Investigator is the person who has the primary responsibility for a research project.

Human Research Participant:
An individual whose data or responses to interventions, stimuli, or questions by a researcher are relevant to answering a research question; also referred to as a "participant", a "subject", or a "research subject".

Minimal Risk Research:
Research in which the probability and magnitude of probable harms implied by participation in the research is no greater than those encountered by participants in the aspects of their everyday life that relate to the research.

Research Proposal:
The written documents submitted to the Douglas College Research Ethics prior to the start of research.

College Resources:
Any materials, equipment, facilities, sites, or services that the College owns or rents, and any personnel that the college employs.

Community engagement:
A process that establishes and interaction between a researcher (or research team) and a community with regard to a research project, and which signifies the intent of forming a collaborative relationship between researchers and communities.

Collaborative research:
Research that involves the cooperation of researchers, institutions, organizations and/or communities, each bringing distinct expertise to a project, and that is characterized by respectful relationships.

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

Participatory research:
Research that includes the active involvement of those who are the subject of the research.

Procedures/Rules Statements

Section 1: Ethics Review

A. **Research Requiring Ethical Review**

1. (Article 2.1 (a); Article 6.11) All research that involves human participants requires review and approval by the REB in accordance with this Policy Statement and the Tri-Council Policy Statement *Ethical Conduct for Research Involving Humans* 2nd Edition (2010), before the research is started, except as stipulated in section A.3 below.
2. (Article 2.1 (b); Article 6.11) Research involving human remains, cadavers, tissues, biological fluids, embryos or fetuses.
3. **Exceptions**
    a. (Article 2.2) Research about a living individual involved in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, archival materials or third-party interviews, is not required to undergo ethics review. Such research only requires ethics review if the subject is approached directly for interviews or for access to private papers, and then only to ensure that such approaches are conducted according to professional protocols and to Articles 2.3 and 10.3 (application) of the Tri-Council Policy Statement.
    b. Research that is making use of data obtained from pre-existing or archival data bases that are in the public domain with no identifying information being used.
    c. Performance review of College employees.

d. Assessments of students carried out within normal educational requirements as approved by Education Council, such as approved curriculum guidelines.
e. Standardized testing conducted by College employees in the normal course of their work where they are qualified to administer such tests.
f. Data collected by the College that relate directly to, and are necessary for, administering, evaluating or seeking to improve an operating program, service or activity of the College.
g. Any research not affiliated with or supported by the College, conducted by College employees on their own time, outside their College role, not using College students or resources, where the researcher's affiliation to the institution is not mentioned. Such research must comply with College policy on conflict of interest (A02.01.01), especially section (C) on compromise of performance.
h. Research involving non-human animal subjects. Researchers must ensure the application of ethical principles and comply with Canadian Council on Animal Care policies and guidelines.

B. **Research Ethics Board**

The mandate of the REB is to ensure that ethical principles are applied to all research involving human participants. Its role is to educate researchers and to review and monitor research proposals and projects. It serves as a consultative body on research ethics and assists in educating employees about research ethics. It has the responsibility for independent multidisciplinary review of research proposals to determine if they meet ethical requirements and to approve them to be initiated or continue.

Douglas College Research Ethics Board Request for Approval Form

1. **Authority of the Research Ethics Board**
   a. (Article 6.1; Article 6.2; Article 6.3)The College mandates the REB to approve, reject, propose modifications to or terminate any proposed or ongoing research involving a human participant that is conducted within or by members of, the College, using the considerations set forth in this Policy, as a minimum standard.
   b. The REB is an independent standing committee with terms of reference approved by Senior Management. The REB's decision to approve or deny proposals for research or standardized testing are made independently and may not be set aside without formal appeal.

2. **Membership of the Research Ethics Board**
   a. (Article 6.4; Article 6.5) The REB shall consist of at least five members, including both men and women, of whom:
      i. at least two are faculty who possess broad expertise in the methods or in the areas of research that are covered by the REB;
      ii. at least one member is knowledgeable in ethics;
      iii. for biomedical research, at least one member is knowledgeable in the relevant law;

iv. at least one member has no affiliation with the College, recruited from the community served by the institution.

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 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 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 to advise on particular proposals that require additional expertise for appropriate review.

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 terms.

f. The REB will elect a Chairperson every two 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 Board. This step should only be contemplated in the face of serious failure to meet the obligations of service to the Board, or 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 on-line tutorial accessed at http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/, or a similar tutorial approved by the REB.

C. **Relationship between Research Ethics Review and Scholarly Review (required for Full Reviews)**
(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. (Article 3.6 application) 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.

4. (Article 2.7) 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. REBs may request that the researcher provide them with the full documentation of scholarly reviews already completed. Where scholarly review is required,

    a. An REB should consider what scholarly review has been applied to a particular research project (by a funder or sponsor, for example, or by a supervisor or thesis committee for student research, or by a permanent peer review committee where it exists);

    b If scholarly review as indicated by the relevant disciplinary tradition has not yet been done, and there is nobody available to do it, the REB should consider either establishing an ad hoc independent peer review committee, or, if the REB has the necessary scholarly expertise, assume complete responsibility for scholarly review. In assuming this responsibility, the REB should not be driven by factors such as personal biases or preferences, and should not reject proposals because they are controversial, challenge mainstream thought, or offend powerful or vocal interest groups.

    The primary test to be used by REBs in evaluating a research project should be ethical acceptability and, where appropriate, relevant disciplinary scholarly standards.

D. **Review Procedure**

1. **Proportionate Approach to Ethics Assessment**
(Article 2.9; Article 6.12) The REB shall adopt a proportionate approach to research ethics review such that, as a preliminary step, the level of review is determined by the level of risk presented by the research: the lower the level of risk, the lower the level of scrutiny (delegated review); the higher the level of risk, the higher the level of scrutiny (full Board review). A proportional approach to assessing the ethical acceptability of the research, at either level of review, involves consideration of the foreseeable risks, the potential benefits and the ethical implications of the research. The REB decides on the level of review for each research proposal.

    Potential harms in research may be social, behavioural, psychological, physical, or economic. They may span the spectrum from minimal to substantial. Harms may be transient, or long-lasting. The perspective of the participants regarding harm may vary from that of researchers, and participants themselves may vary in their reaction to research. The REB and researchers will attempt to assess harm from the perspective of the participants as much as possible, including both the magnitude and the probability of the occurrence of harm. Research in some disciplines may also present risks that go beyond the individual to include the interests of communities, societies, or other groups. The REB has a special obligation to individuals or groups whose situation or circumstances make them vulnerable in the context of a specific research project, and to those who live with relatively high levels of risk on a daily basis. Their inclusion in research should not exacerbate their vulnerability.

a. Proposals are reviewed and may be approved through one of the means listed below. Regardless of the review strategy, the REB remains responsible for the ethics of all research involving human participants that is carried out at and by the College.

i. **Full Review**
Where a proposal poses more than minimal risk (as defined by the Tri-Council Guidelines in (Article 2.B), the REB will assess the harms and benefits of the proposed research project, may determine if the research design is capable of answering the research questions, and will ensure that the research procedures and materials conform to established ethical standards.

ii. **Delegated Review** (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. **Local (Course) Review (Research Conducted by Students as Part of Course Requirements)** (Results of these reviews will be reported back to the full REB in a timely manner.)
Research which is conducted by students under the supervision of an instructor as part of an approved course outline does not need approval from the Research Ethics Board. Instead, the appropriate Faculty Education Committee 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 earlier.

iv. **Review Procedure for On-going Research**

a. (Article 6.14) 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.

b. (Article 6.14) The REB shall determine the level at which continuing ethics review occurs in accordance with a proportionate approach to ethics review.

c. (Article 6.14) 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.

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 predetermined. These reports should include an assessment of how closely the researcher and the research team have complied with the ethical safeguards initially proposed.

e. In accordance with the principle of proportionate review, research that exposes participants to minimal risk or less requires only a minimal review process. The continuing review of research exceeding the threshold of minimal risk, in addition to annual review might include:

i. formal review of the free and informed consent process;
ii. establishment of a safety monitoring committee;
iii. periodic review by a third party of the documents generated by the study;
iv. review of reports of adverse events;
v. review of patients' charts; and
vi. a random audit of the process of free and informed consent.

b. To undergo REB review, researchers will submit to the REB:

i. The research proposal, in sufficient detail to permit the REB to make an assessment of its ethical acceptability;
ii. Experimental protocol (where appropriate);
iii. Informed consent statement and forms (as necessary). Normally, participants must be given a copy of the informed consent form which they have signed;
iv. Copies of questionnaires and research instruments (where appropriate);
v. Statement of formal acknowledgement and/or approval of any agencies or companies whose co-operation is needed to conduct the research or whose support is being or is provided in connection with the research (where applicable);

vi. Copies of any ethical guidelines, other than those approved by the REB, used in preparing the proposal;

vii. Such other material or information as the REB may request.

2. **Meetings and Attendance**
   a. (Articles 6.10)The REB will meet regularly and as needed to review requests and carry out REB business. It is necessary for members to attend and participate in face to face meetings.

   b. A quorum for committee purposes for a full review is at least 4 members. Where possible, the REB will reach decisions by consensus; otherwise a simple majority will prevail. The Chair will not vote, except in the event of a tie.

   c. The REB Chair will arrange the meetings, distribute relevant documents and organize the recording and distribution of minutes. He/she will also ensure that all minutes, and relevant records are maintained securely.

3. **Record Keeping**
   a. (Article 6.17) Minutes of all REB meetings shall be prepared and maintained by the REB. The minutes shall clearly document members in attendance, the REB's decisions and any dissents, and the reasons for them. In order to assist internal and external audits or research monitoring and to facilitate reconsideration or appeals, the minutes are accessible to authorized representatives of the College, researchers and funding agencies.

   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
      v. Written procedures for the REB.

4. Standards for retention and archiving of records may vary according to discipline, but the College requires that records related to research must be retained for at least five years after completion of the research. Where legal, scholarly, or other standards mandate a longer period of retention, researchers are expected to comply with these standards.

5. **Decision Making**
   a. (Article 6.13) The REB review shall be based upon fully detailed research proposals or, where applicable, progress reports. The REB will function impartially, provide a fair hearing to those involved and provide reasoned and appropriately documented opinions and decisions. The REB will accommodate reasonable requests from researchers to participate in discussions about their proposals, but not to be present when the REB is making its decision. When the REB is considering a negative decision, it shall provide the researcher with all the reasons for doing so and give the researcher an opportunity to reply before making a final decision.

   b. Final decisions in the full review that are based on consensus or majority quorum (i.e. at least 4 members present) will be adopted only if the members attending the meeting possess the range and background outlined in section B2 of this policy.

   c. The REB will notify the researchers in writing of its decision to:
      i. Approve the proposed research activity as submitted; or
      ii. Require minor modifications of the proposed research activity. The resubmitted proposal will be reviewed by the Chair of the REB; or
      iii. Require significant modifications or additional information or major revisions. The resubmitted proposal will be reviewed by the REB; or
      iv. Disapprove the proposed research activity.

   d. The Chair of the REB will submit an annual report to Senior Management listing the number of proposals reviewed, approved and denied.

6. **Reconsideration**
   a. (Article 6.18) Researchers have the right to request, and the REB has the obligation to provide, reconsideration of decisions affecting a research project.

   b. The REB will be guided by principles of natural and procedural justice in their decision-making. Such principles include providing a reasonable opportunity to be heard, an explanation of the reasons for opinions or decisions, and the opportunity for rebuttal, fair and impartial judgment, and reasoned and written grounds for the decisions.

7. **Appeals**
   Researchers have the right to appeal a decision taken by the REB by submitting in writing their reasons to the Chair. Such appeals will then be submitted to the Research Ethics Board of the University of the Fraser Valley with which Douglas College has a formal agreement to perform this function. The decision of that Research Ethics Board shall be final. Please see Appendix 1 - Research Ethics Board Appeals for details of this agreement.

8. **Conflicts of Interest**
    a. (Article 7.3) If the REB is reviewing research in which a member of the REB has a personal interest in the research under review (e.g., as a researcher or as an entrepreneur), conflict of interest principles require that the member not be present when the REB is discussing or making its decision. The REB member may disclose and explain the conflict of interest and offer evidence to the REB provided the conflict is fully explained to the REB, and the proposer of the research has the right to hear the evidence and to offer a rebuttal.

    b. Disclosure of the conflict of interest will comply with the Douglas College Conflict of Interest Policy.

9. **Review of Multi-Centered Research**
    Principles of institutional accountability require that each local REB to be responsible for the ethical acceptability of research undertaken within its institution. However, in multi-centered research, when several REBs consider the same proposal from the perspectives of their respective institutions, they may reach different conclusions on one or more aspects of the proposed research. To facilitate coordination of ethics review, when submitting a proposal for multi-centered research, the researcher may want to distinguish between core elements of the research which can be altered without invalidating the pool of data from the participating institutions " and those elements that can be altered to comply with local requirements without invalidating the research project.

    For research posing more than minimal risk, REBs may also wish to coordinate the review of multi-centered projects, and to communicate any concerns that they may have with the others REBs reviewing the same project.

10. **Review of Research in Other Jurisdictions or Countries**
    a. (Article 8.3) Research to be performed by members of the College (employees, researchers, students) outside the jurisdiction of the College shall undergo prospective ethics review both (a) by the College REB; and (b) by the REB, where such exists, with the legal responsibility and equivalent ethical and procedural safeguards in the country or jurisdiction where the research is to be done.

    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

Section 2: Free, Informed, and Ongoing Consent

A. **Requirement for Free, Informed, and Ongoing Consent**

1. (Article 3.3; Article 3.5) 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.

2. (Article 3.12) 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.

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. (Article 3.7, Application) 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 alteration of the requirements for consent if the participants are informed of the probability of being randomly assigned to any arm of the study.

B. **Voluntariness**

(Article 3.1) Free and informed consent must be voluntarily given, without manipulation, undue influence or coercion.

C. **Naturalistic Observation**

(Article 10.3, Application) REB review is normally required for research involving naturalistic observation. However, research involving observation of participants in, for example, political rallies, demonstration or public meetings, should not require REB review, since it can be expected the participants are seeking public visibility.

D. **Informing Potential Participants**

1. **General Conditions**

(Article 3.2) Researchers shall provide, to prospective participants or authorized third parties, full and frank disclosure of all information relevant to free and informed consent. In addition, (Article 3.3) consent shall be an ongoing process. 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:

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 conflicts of interest 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. The identity and contact information of the appropriate individual(s) outside the research team whom participants may contact regarding possible ethical issues in the research;

i. An indication of what information will be collected about participants and for what purposes; an indication of who will have access to information collected about the identity of participants, a description of how confidentiality will be protected, a description of the anticipated uses of data; and information indicating who may have a duty to disclose information collected, and to whom such disclosures could be made;

j. Information about any payments, including incentives for participants, reimbursement for participation-related expenses and compensation for injury;

k. A statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm; and

l. In clinical trials, information on stopping rules and when researchers may remove participants from trial.

E. **Capacity**

1. (Article 3.8; Article 4.6) Subject to applicable legal requirements, individuals who lack capacity to consent to participate in research shall not be inappropriately excluded from research. Where a researcher seeks to involve individuals in research who do not have capacity to consent for themselves, the researcher shall, in addition to fulfilling the conditions in sections 2 and 3 below, satisfy the REB that:
   a. The research question can only be addressed using individuals within the identified group(s); and
   b. Free and informed consent will be sought from their authorized representative(s); and
   c. The research does not expose them to more than the minimal risk without the prospect for direct benefits for them;

2. (Article 3.9) For research involving individuals who lack the capacity, either permanently or temporarily, to decide for themselves whether to participate, the REB shall ensure that, as a minimum, the following conditions are met:
   i. the researcher involves participants who lack the capacity to consent on their own behalf to the greatest extent possible in the decision-making process;
   ii. the researcher seeks and maintains consent from authorized third parties in accordance with the best interests of the persons concerned;
   iii. the authorized third party is not the researcher or any other member of the research team;
   iv. The researcher demonstrates that the research is being carried out for the participant's direct benefit, or for the benefit of other persons in the same category. If the research does not have the potential for direct benefit to the participant but only for the benefit of the other persons in the same category, the researcher shall demonstrate that the research will expose the participant to only a minimal risk and minimal burden, and demonstrate how the participant's welfare will be protected throughout the participation in research; and

v. When authorization for participation was granted by an authorized third party, and a participant acquires or regains capacity during the course of research, the researcher shall promptly seek the participant's consent as a condition of continuing participation.

3. (Article 3.10) Where free and informed consent has been obtained from an authorized third party and in those circumstances where the legally incompetent individual understands the nature and consequences of the research, the researcher shall seek to ascertain the wishes of the individual concerning participation. The potential participant's dissent will preclude his or her participation.

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 only be required 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 application for ethics review (e.g. child no longer lives with parent, there is no invasion of privacy or sensitive issue involved, etc.).

F. **Research in Emergency Health Situations**

1. (Article 3.8) Subject to all applicable legislative and regulatory requirements, research involving emergency health situations shall be conducted only if it addresses the emergency needs of individuals involved, and then only in accordance with criteria established in advance of such research by the REB. The REB may allow research that involves health emergencies to be carried out without the free and informed consent of the participant or of his or her authorized third party if ALL of the following apply:
   a. A serious threat to the prospective participant requires immediate intervention; and
   b. Either no standard efficacious care exists or the research offers a real possibility of a direct benefit to the participant in comparison with standard care; and
   c. Either the risk of harm is not greater than that involved in standard efficacious care, or it is clearly justified by the direct benefits to the participant; and
   d. The prospective participant is unconscious or lacks capacity to understand risks, methods and purposes of the research; and
   e. Third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and

2. When a previously incapacitated participant regains capacity, or when an authorized third party is found, free and informed consent shall be sought promptly for continuation in the project and for subsequent examinations or tests related to the study.

Section 3 Privacy and Confidentiality

A. **Accessing Private Information: Personal Interviews**
(Article 2.2; Chapter 5, Section A) Subject to the exceptions in Section 1 above (Ethics Review), researchers who intend to interview a human participant to secure identifiable personal information shall secure REB approval for the interview procedure used and shall ensure the free and informed consent of the interviewee as required in Section 2 above. REB approval is not required for access to publicly available information or materials, including archival documents and records of public interviews or performances.

B. **Accessing Private Information: Surveys, Questionnaires and Collection of Data**
1. (Article 3.3) Researchers shall secure REB approval for obtaining identifiable personal information about participants. Approval for such research shall include such considerations as:
   a. The type of data to be collected;
   b. The purpose for the which the data will be used;
   c. Limits on the use, disclosure and retention of the data;
   d. Appropriate safeguards for security and confidentiality;
   e. Any modes of observation (e.g., photographs or videos) or access to information (e.g., sound recordings) in the research that allow identification of particular participants;
   f. Any anticipated secondary uses of identifiable data from the research;
   g. Any anticipated linkage of data gathered in the research with other data about participants, whether those data are contained in public or personal records; and
   h. Provisions for confidentiality of data resulting from the research.

C. **Secondary Use of Data**
1. (Article 5.5) If identifying information is involved, REB approval shall be sought for secondary uses of data. Researchers may gain access to identifying information if they have demonstrated to the satisfaction of the REB that:
   a. Identifying information is essential to the research; and
   b. They will take appropriate measures to protect the privacy of the individuals, to ensure the confidentiality of the data, and to minimize harms to subjects.
   c. Individuals to whom the data refer have not objected to secondary use.

2. (Article 5.6) The REB may also require that a researcher's access to secondary use of data involving identifying information be dependent on:
    a. The informed consent of those who contributed data or of authorized third parties; or
    b. An appropriate strategy for informing the subjects; or
    c. Consultation with representatives of those who contributed data.
    d. (Article 5.6) Researchers who wish to contact individuals to whom data refer shall seek the authorization of the REB prior to contact.

D. **Data Linkage**
(Article 5.7) The implications of approved data linkage in which research subjects may be identifiable shall be approved by the REB.

Section 4: Conflicts of Interest for Researchers

(Article 7.3; Article 7.4) Researchers and REB members shall disclose actual, perceived or potential conflicts of interest to the REB. The REB will develop and use mechanisms to address conflict of interest, whether real or apparent.

Section 5: Inclusion in Research

A. (Article 4.1) Taking into account the scope and objectives of their research, researchers should be inclusive in selecting participants. Researchers shall not exclude individuals from the opportunity to participate in research on the basis of attributes such as culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender or age, unless there is a valid reason for the exclusion.

B. This article is not intended to preclude research focused on a single living individual (such as in a biography) or on a group of individuals who share a specific characteristic.

C. (Article 4.2) Women shall not automatically be excluded from research solely on the basis of gender or sex. (Article 4.3) Women shall not be inappropriately excluded from research solely on the basis of their reproductive capacity, or because they are pregnant or breastfeeding.

D. (Article 4.4) Children shall not be inappropriately excluded from research solely on the basis of their age or developmental stage. The inclusion of children in research is subject to Section 2 E above, for participants who lack legal capacity to consent for themselves.

E. Elderly people shall not be inappropriately excluded from research solely on the basis of their age.

F. (Article 4.6) Subject to the provisions of Articles 3.8 to 3.10, those who are not competent to consent for themselves shall not be automatically excluded from research that is potentially beneficial to them as individuals or to the group that they represent.

G. Given the unique legal status of Aboriginal peoples (including First Nations, Inuit, and Métis) in the Canadian Constitution, Douglas College insists that research with Aboriginal peoples must be respectful of Aboriginal traditions including collective rights, interests, and responsibilities. It is expected that consent will be freely given by

individuals, and it is also expected that researchers are aware that respect may extend to the ancestors of Aboriginal participants and to the natural world. Issues of justice, and particularly an awareness of significant imbalances of power that may exist in relationships created through Aboriginal research, must also be acknowledged.

It is expected that researchers working with Aboriginal peoples and in Aboriginal communities will acknowledge that Aboriginal peoples have unique histories, cultures, and traditions. It is noted that Aboriginal communities are rarely homogenous in their outlooks. Time should be built into projects to allow for the establishment of personal relationships. Local practices must be considered when planning and conducting research. Permission for projects must be sought at multiple levels including, at minimum, community and individual levels. Family permission may also be necessary. It is expected that researchers will adhere to local processes where possible and ethical. Flexibility is important.

With this in mind, Douglas College requires that researchers working with Aboriginal peoples must:

1. Receive REB approval
2. Provide the REB with a plan for community engagement (or evidence of such engagement)
3. Lay out clearly and in writing a research agreement with the community
4. Consider collaborative research, participatory research, and research that benefits the community or is relevant to the community
5. Engage the community and the individual participants and recognize diverse interests in communities
6. Determine the extent of community participation jointly with individuals and their communities.
7. Respect the governing authorities when conducting research on Aboriginal lands.
8. Engage, where possible, Aboriginal organizations
9. Acknowledge the complex authority structures present in Aboriginal communities including the possibility of multiple avenues of endorsement and rejection of projects
10. Be informed about and respectful of community customs and practices
11. Build capacity-building into proposals, where possible
12. Recognize the role of elders and knowledge holders in Aboriginal communities
13. Address privacy issues of both individuals and their contributions to the research

14. Afford community representatives a chance to participate in interpretation of the data and review research findings before project completion

15. Discuss intellectual property rights, ownership, copyright with participants and communities (including for biological materials)

Section 6: Clinical Trials

A. **Phases of Pharmaceutical Research**

1. (Article 11.1) Phase 1 non-therapeutic clinical trials shall undergo both stringent review and continuous monitoring by an REB independent of the clinical trials sponsor.
2. (Article 11.1) In combined Phase I/II clinical trials, researchers and the REB shall carefully examine the integrity of the free and informed consent process. Where appropriate, the REB may require an independent monitoring process.
3. (Article 11.11) The REB shall examine the budgets of the clinical trials to assure that ethical duties concerning conflict of interest are respected.
4. (Article 11.2) The use of placebo controls in clinical trials is generally unacceptable when standard therapies or interventions are available for a particular patient population. In those cases where use of placebo is permitted, research proposals submitted to the REB shall include justification of both the trial design and the use of placebo.

Section 7: Human Genetic Research

A. **Individuals, Families and Biological Relatives**

(Article 13.3) The genetics researcher shall seek free and informed consent from the individual and report results to that individual if the individual so desires. (Article 13.1) The standards for ethics review, consent, privacy, and confidentiality apply equally to human genetic research.

B. **Privacy, Confidentiality, Loss of Benefit and Other Harms**

1. (Article 13.7) The researcher and the REB shall ensure that the results of genetic testing and genetic counseling records are protected from access by third parties, unless free and informed consent is given by the participant. Family information in a data bank shall be coded so as to remove the possibility of identification of participants within the bank itself.
2. (Article 13.5; Article 13.6) Researchers and genetic counselors involving families or groups in research studies shall reveal potential harms to the REB and outline how such harms will be dealt with as part of the research project.

C. **Genetic Counseling**

(Article 13.4) Genetics researchers and the REB will ensure that the research protocol make provision for access to genetic counseling for the participants, where appropriate.

D. **Gene Alteration**
(Chapter 13 Section G) Gene transfer research that involves alteration of human germ line cells is governed by the *Assisted Human Reproduction Act*. This Act prohibits knowingly altering the genome of a human cell in a living being or in vitro embryo, such that the alteration is capable of being transmitted to descendants.

E. **Banking of Genetic Material**
(Article 13.7) Though the banking of genetic material is expected to yield benefits, it may also pose potential harms to individuals, their families and the groups to which they may belong. Accordingly, researchers who propose research involving the banking of genetic material have a duty to satisfy the REB and prospective research participants that they have addressed the associated ethical issues, including confidentiality, privacy, storage, use of the data and results, withdrawal by the participant, and future contact of participants, families and groups.

F. **Commercial use of Genetic Data**
(Article 3.2, Application (e); Article 13.7) At the outset of a research project, the researcher shall discuss with the REB and the research participant the possibility and/or probability that the genetic material and the information derived from its use may have potential commercial uses.

Section 8: Research Involving Human Gametes, Embryos or Foetuses

A. **Research Involving Human Gametes**
1. (Article 12.1) Researchers shall obtain free and informed consent from the individual whose gametes are to be used in research.
2. (Article 12.6 (b) In research, it is not ethical to use ova or sperm that have been obtained through commercial transactions, including exchange for service.
3. (Chapter 12, Section F) It is not ethically acceptable to create, or intend to create, hybrid individuals by such means as mixing human and animal gametes, or transferring somatic or germ cell nuclei between cells of humans and other species.

B. **Research involving Human Embryos**
1. (Article 12.8) It is not ethically acceptable to create human embryos specifically for research purposes. However, in those cases where human embryos are created for reproductive purposes, and are subsequently no longer required for such purposes, research involving human embryos may be considered to be ethically acceptable, but only if all of the following apply:
    a. The ova and sperm from which they are formed were obtained in accordance with Articles 12,1 and 12.6 (b)
    b. The research does not involve the genetic alteration of human gametes or embryos.; Embryos exposed to manipulations not directed specifically to their ongoing normal development will not be transferred for continuing pregnancy; and

c. Research involving human embryos takes place only during the first 14 days after their formation by combination of the gametes.

2. (Chapter 12, Section F) It is not ethically acceptable to undertake research that involves ectogenesis, cloning human beings by any means including somatic cell nuclear transfer, formation of animal/human hybrids or the transfer of embryos between humans or other species.

Section 9: Human Tissue

A. **Free, Informed and Ongoing Consent**

1. (Article 12.1) Research proposing the collection and use of human tissues requires REB approval. Amongst other things the researcher must demonstrate the following to the REB:
   a. That the collection and use of human tissues for research purposes shall be undertaken with the free and informed consent of competent donors
   b. In the case of incompetent donors, free and informed consent shall be by an authorized party; and
   c. In the case of deceased donors, free and informed consent shall be expressed in a prior directive or through the exercise of free and informed consent by an authorized third party.
2. (Article 12.2) For the purpose of obtaining free and informed consent, researchers who seek to collect human tissue for research shall, as a minimum, provide potential donors or authorized third parties information about:
   a. The purpose of the research;
   b. The type and amount of tissue to be taken, as well as the location where the tissue is to be taken;
   c. The manner in which the tissue will be taken, the safety and invasiveness of the acquisition, and the duration and conditions of preservation;
   d. The potential uses for the tissue including any commercial uses;
   e. The safeguards to protect the individuals' privacy and confidentiality;
   f. Identifying information attached to specific tissue, and the potential for traceability; and
   g. How the issue of tissue could affect privacy.

B. **Previously Collected Tissue**

1. (Article 12.3) When identification is possible, researchers shall seek to obtain free and informed consent form individuals or from their authorized third parties, for the use of their previously collected tissue. The provisions of Article 12.3 also apply here.
2. (Article 12.3) When collected tissue has been provided by persons who are not individually identifiable (anonymous and de-identified tissue) and where there are no potential harms to them, there is no need to seek donors' permission to use their tissue for research purposes, unless applicable law so requires.

Appendix 1 - Research Ethics Board Appeals