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| Procedures Name | Ethical Conduct for Research Involving Humans |
| Procedures No. | F.1.1 |
| Approval Body | Board of Governors |
| Policy Sponsor | Vice President, Academic & Applied Research |
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RESEARCH ETHICS BOARD

A. Mandate

1. The President delegates the Vice President, Academic and Research (VPAR), as the administrator responsible for establishing the REB to conduct ethics review and reconsiderations, appointing members to the REB, and providing administrative and financial resources that ensure the REB can fulfil its duties.
2. The REB is an independent body responsible for reviewing the ethical acceptability of all proposed and ongoing research that involves human participants conducted within the jurisdiction of VCC or under its auspices.
3. The College mandates the REB to approve, reject, and propose modifications to, or terminate any proposed or ongoing research involving human participants that is conducted within or by members of the College using the considerations set forth in the Tri-Council Policy Statement as a minimum standard. The REB's decision to approve or deny proposals for research is made independently and may not be set aside without formal appeal.
4. The REB serves as a consultative body on research ethics and assists in educating the VCC community including faculty, staff and students about research ethics.

B. Equity, Diversity and Inclusion

5. VCC is committed to the work of decolonization, accessibility and inclusivity for all. The Research Ethics Board membership will strive, at a minimum, to reflect diversity in racial, ethnic, and gender composition.

C. Membership of the Research Ethics Board

6. The REB will consist of at least five (5) members, including broad gender representation, of whom:
 - a. at least two (2) are faculty who possess broad expertise in the methods or in the areas of research that are covered by the REB;
 - b. at least one (1) member is knowledgeable in ethics;
 - c. for biomedical research, at least one (1) member is knowledgeable in the relevant law; and

- d. at least one (1) member has no affiliation with the College, recruited from the community served by the institution.
7. VCC will designate at least one seat for an Indigenous member appointed to the REB.
8. Community members will receive an honorarium as per VCC policy B.1.13 Honoraria.
9. To ensure the independence of REB decision making, VCC senior administrators will not serve on the REB.
10. Each member should be appointed to fulfill the formal requirements outlined in paragraph 6. Except for community members, all members of the REB will have current or recent experience conducting research with humans and/or research ethics expertise. Membership will strive to represent the breadth of disciplines at VCC. The VPAR shall maintain general records related to REB membership and qualifications of members (a copy of the CV of each member along with any documentation of research ethics training).
11. Appointments shall be made by the VPAR. There will be an annual call-out for new membership indicating areas of expertise required. From this pool of applicants, VPAR may choose to select new members. New members will complete the current TCPS CORE (or equivalent) training and receive an orientation from the REB Chair.
12. The term of appointment for each member will be three years, for two consecutive terms maximum. Members may be re-appointed to REB after a three-year break. Appointment of members will be staggered when possible, to help maintain continuity and ensure diversity of opinion.
13. The REB may remove a member with a 2/3 vote.
14. The REB may from time to time also call on ad hoc advisors if it lacks the specific expertise or knowledge to review the ethical acceptability of a research proposal competently. Ad hoc advisors will not be counted in the quorum for an REB, nor be allowed to vote on REB decisions.
15. The REB will elect a Chair from among its membership. The position is renewable on a two-year term for a maximum of six years. The Chair must be a VCC employee with previous REB experience. If the REB is unable to elect a Chair from among their membership, the VPAR will recommend one or more candidates for appointment.
16. If the Chair is temporarily unable to perform their duties, the VPAR will be informed and the REB will elect one from among their membership to be appointed temporary Chair for the duration of the term.

D. Meetings and Attendance

17. The REB will meet at a minimum of six times a year and additionally as needed to review requests, provide educational training for members and carry out REB business.
18. Regular attendance by REB members at meetings is required. Members will notify the Chair in a timely manner if unable to attend the meetings. Two unexplained absences may be construed as notice of resignation.
19. A quorum for committee purposes for a full review is at least four members with appropriate expertise, excluding the chair. 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. Meetings are held in-camera during the decision-making process of research proposals undergoing a full board review.

20. The Chair will provide regular updates of delegated reviews and brief rationale for decisions to the REB.
21. The REB will establish and publish a yearly meeting schedule and deadlines for submissions to be considered at each meeting.

E. Record Keeping

22. Minutes of all VCC REB meetings will be prepared and maintained by the Chair or designate. The minutes will clearly document the Committee's decisions and any dissents and the reasons for them. Minutes are accessible to authorized representatives of the institution, researchers, and funding agencies.
23. The REB Chair (or designate) is responsible for the preparation, maintenance, and secure storage of adequate documentation of REB activities, including the following:
 - a. Copies of all research proposals reviewed, REB members who completed the review, 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;
 - b. Records of continuing review activities;
 - c. Copies of all correspondence between the REB and the researchers;
 - d. A list of REB members and roles of expertise;
 - e. Standard operating procedures (SOPs) for the REB.
24. The REB will submit an annual report to the VPAR and Education Council, listing the number of proposals reviewed, approved, and denied and other annual activities of the REB, such as further education/training of members or education provided to faculty.
25. All such required records will be retained for seven years, according to the VCC Records Retention schedule. Records relating to research that is conducted will be retained for seven years upon completion of the research, or longer if mandated by law.

ETHICS REVIEW

26. Research Requiring Ethical Review

- a. Unless specifically excluded under paragraph 27, any research conducted by an individual under the auspices of Vancouver Community College (VCC) is subject to mandatory ethics review and approval prior to the commencement of the research if it involves:
 - i. living human participants or
 - ii. research on human biological materials (tissues, organs, plasma, serum, DNA, RNA, proteins, cells, skin, hair, nail clippings, urine, saliva and other bodily fluids (TCPS2, Article 2.1) or materials related to human reproduction (embryos, fetuses, fetal tissues and human reproductive materials (TCPS2, Article 2.1) derived from living or deceased individuals.

27. Activities not requiring REB review

- a. Research that relies on publicly available information when: (a) the information is legally accessible to the public and appropriately protected by law; or (b) the

information is publicly accessible and there is no reasonable expectation of privacy.

- b. Research that exclusively uses data obtained from pre-existing or archival databases that are in the public domain with no identifying information attached to records
 - c. Research involving observation of people in public places where: (a) there is no intervention staged by the researcher or direct interaction with the individuals or groups; (b) individuals or groups targeted for observation have no reasonable expectation of privacy; and (c) any dissemination of research results does not allow identification of specific individuals.
 - d. Research that exclusively uses anonymous secondary use information or anonymous human biological materials, so long as any data linkage, recording, or dissemination of results does not generate identifiable information.
 - e. Quality assurance and quality improvement studies, program evaluation activities and performance reviews, or testing within the normal educational requirements when used exclusively for assessment, management or improvement purposes.
 - f. Creative practices through which art is made or interpreted, provided these processes are not used to obtain responses from participants that will be analyzed to answer a research question.
 - g. Any research not affiliated with or supported by the College (i.e., conducted by College employees or students on their own time, outside their College role, not using College employees, students, or resources).
28. If a researcher is uncertain whether contemplated research does or does not require approval under this policy, then the researcher shall consult with the Chair of the VCC REB.

Review Procedure

29. Application Process

- a. The principal investigator is responsible for submitting research proposals to the REB for review prior to initiating research. To undergo REB review, researchers will submit electronically the Request for Ethics Review (Form 1).
- b. The principal investigator must disclose any real or perceived conflict of interest to the REB at the time of application.
- c. Prior to VCC REB review, researchers who plan research involving First Nations, Inuit and Métis peoples, regardless of where they reside and whether their names appear on an official register, must consult the TCPS (Chapter 9) for additional guidance on such research. These communities have unique histories, cultures and traditions. Among the key principles that must be respected in the research plan are:
 - i. Need for community engagement;
 - ii. Respect for First Nations, Inuit and Métis governing authorities;
 - iii. Engagement with organizations and communities of interest;
 - iv. Recognition of complex authority structures;

- v. Recognition of diverse interests within communities;
- vi. Respect for community customs and codes of practice;
- vii. Requirement of mutual benefits in research; and
- viii. Recognition of the role of elders and other knowledge holders.

30. Review of Multi-Jurisdictional Research

- a. The VCC REB is responsible for the ethical acceptability of research undertaken within VCC's jurisdiction or under its auspices, including research conducted by staff or students of VCC outside the institute's jurisdiction or outside Canada. In such cases, the research must be reviewed by VCC's REB as well as the REB(s) of any partner institution or site. Where VCC or TCPS standards differ from that of the other institution or the other jurisdiction, VCC requires its researcher to comply with the higher standards.

31. Determining the Level of Research Ethics Review

- a. The REB applies a *proportionate approach* to ethics review based on the general principle that the more potentially invasive or harmful the proposed research, the greater the care necessary in its review. Potential harm is usually understood in relation to risks, which are defined in terms of the magnitude of harm and the probability of its occurrence. Applications to the REB may be placed in one of the review categories below.

32. Full Board Review

- a. Where a proposal poses more than minimal risk (as defined by the Tri-Council Guidelines in Articles 2.9 and 6.12), the REB will:
 - i. assess the harm and/or benefits of the proposed research project,
 - ii. determine if the research design can answer the research questions, and
 - iii. ensure that the research procedures and materials conform to established ethical standards.
- b. A quorum of the REB Chair and four voting REB members, who meet the minimum requirements of representation and expertise necessary to provide an adequate research ethics review of the proposal(s) under consideration, will review the proposal.

33. Delegated Review

- a. Where a proposal
 - i. poses only minimal risk,
 - ii. has been approved elsewhere by a Tri-Council policy-compliant REB, and/or
 - iii. is research conducted by students under the supervision of an instructor as part of an approved course research proposal (course designation) designed to fall under the minimal risk category,
- b. the REB Chair will assign a minimum of two members to review the proposal and its conformity to established research ethics standards and practices. Every effort will be made to transmit a decision within ten (10) working days.

34. Delegated Review of Course-Based Research

- a. An instructor wishing to offer a course that requires or permits students to participate in research involving humans solely for pedagogical purposes shall submit to the REB Chair an application that includes the following information:
 - i. course description;
 - ii. course syllabus;
 - iii. general description of the type(s) of research projects that are likely to be part of the course;
 - iv. description of the instructor's training and familiarity with research ethics including completion of the current TCPS CORE tutorial or equivalent;
 - v. means by which the students in the course are made familiar with appropriate ethical standards
 - vi. means by which the students submit their research to the instructor;
 - vii. means by which students' research plans are assessed and approved by the instructor (including consent forms, data, questionnaires, etc.)
 - viii. means by which the conduct of the research is monitored by the instructor; and
 - ix. any other relevant information.
- b. The delegated process described above does not apply to:
 - i. thesis or project courses where the research is the key evaluative component within the course,
 - ii. course-based research by students which is above minimal risk, or
 - iii. research which forms a component of an instructor's own research.
- c. Where students are carrying out research that is part of a faculty member's own research program, this research proposal must be reviewed by the REB as in the Full Board Review, or Delegated Review procedure described above.
- d. The Chair of the REB or someone delegated by the Chair (including an REB member, or a non-REB member within the department/faculty with appropriate experience and expertise) shall have the authority to conduct an ethical review of course-based research involving humans conducted solely for pedagogical purposes. The REB Chair or delegate shall only approve course-based research involving humans that involves minimal risk to participants.
- e. The records related to Course-Based Research Ethics Review shall be stored by the Office of the VPAR and be retained for a minimum of seven (7) years.
- f. Instructors must re-submit a request for approval whenever there are material changes planned in any of the elements listed above, or every 2 years (whichever is greater). Re-submission will be required when the official course outline is reviewed according to the normal review schedule, if there are any material changes.
- g. Extension of approval to a new instructor requires submission of the form "Course-Based Research Extension of Approval".

35. Decision Making

- a. The REB review will 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.

36. Conflicts of Interest

- a. If the REB is reviewing research in which an REB member 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.
- b. REB members will disclose disputes, conflicts, or collaborations with researchers (within the last two years) whose research is being reviewed, to the REB Chair. The REB Chair will make a determination as to whether they may participate in the review.

37. The REB will notify the researchers in a timely manner in writing of its decision to:

- a. Approve the proposed research activity as submitted; or
- b. Require minor modifications of the proposed research activity. The resubmitted proposal will be reviewed by the Chair or delegate of the REB; or
- c. Require significant modifications or additional information or major revisions. The resubmitted proposal will be reviewed by the REB; or
- d. Reject the proposed research activity.

38. Reconsideration of Research Ethics Board Decisions

- a. Researchers have the right to request, and the REB has the obligation to provide, reconsideration of decisions affecting a research project. The principal investigator must submit to the REB a written request for reconsideration, with rationale. The onus is on researchers to justify the grounds on which they request reconsideration by the REB and to indicate any alleged breaches to the established research ethics review process, or any elements of the REB decision that are not supported by this Policy.
- b. The REB will provide a response in writing within 7 business days.

39. Formal Appeals

- a. VCC will enter into a Memorandum of Understanding (MOU) with another B.C. post-secondary institution with a Research Ethics Board for the purpose of identifying an appeal board for VCC REB.
- b. If a request for a reconsideration is unsuccessful in resolving the disagreement and the REB has refused ethics approval of research, the principal investigator has the right to a formal appeal of the REB's decision. A principal investigator wishing to formally appeal a decision of the VCC REB to reject a research proposal or to rescind approval of on-going research must provide the VPAR with the following documents within 30 business days of receipt of notification of the REB's decision following its reconsideration:
 - i. the final application, as submitted to the VCC REB, and
 - ii. a statement of the basis of the appeal (procedural, substantive, or both) and the rationale for the appeal.
- c. The REB Chair will provide to the VPAR the REB materials specified in the MOU.

- d. The VPAR will submit all the materials to the REB Appeal Board within five working days of receipt of the materials described above.
- e. Decisions of the Appeal Board will be final and binding upon VCC and the Research Project Investigators.

40. Continuing Ethics Research Review

- a. The REB will maintain continuing oversight of the research after the project has received initial ethical approval. The REB will make the final determination as to the nature and frequency of continuing research ethics review in accordance with a proportionate approach to research ethics review.
- b. At minimum, continuing research ethics review will consist of an annual status report (for multi-year research projects), and an end-of-study report (projects lasting less than one year).
- c. Researchers will report to the REB any unanticipated issue or event that may increase the level of risk to participants or that has other ethical implications that may affect participants' welfare.
- d. A report, in the format specified by the REB, must be submitted by the principal investigator to the REB within 60 days of the completion of data collection Requirement for Free, Informed and Continuing Consent.

41. This policy will be reviewed at least once every five years.

RELATED RESOURCES

F.1.1 Ethical Conduct for Research Involving Humans Policy