PROCEDURES

Title	**Ethical Conduct for Research Involving Humans**
Policy No.	F.1.1
Approval Body	Board of Governors
Policy Sponsor	Vice President, Academic & Research
Last Revised/Replaces	April 5, 2013; April 26, 2007
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Section 1: Ethics Review

A. Research Requiring Ethical Review

1. Unless specifically excluded under Item A.2 below, any research conducted by an individual under the auspices of Vancouver Community College (VCC) involving (a) living human participants or (b) research on human biological materials [1]or materials related to human reproduction[2] derived from living or deceased individuals is subject to mandatory ethics review and approval prior to the commencement of the research.
2. Exceptions
    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 being used.
    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.

[1] "tissues, organs, plasma, serum, DNA, RNA, proteins, cells, skin, hair, nail clippings, urine, saliva and other bodily fluids" (*TCPS 2*, Article 2.1)
[2] "embryos, fetuses, fetal tissues and human reproductive materials" (*TCPS 2*, Article 2.1)

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).

If a researcher is uncertain whether contemplated research does or does not require approval under this policy, then the researcher shall consult the Chair of the VCC-REB.

B. Review Procedure

3. Proportionate Approach to Ethics Assessment
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.
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 review of all research involving human participants that is carried out at the College.

4. Full Review
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: (a) assess the harm and/or benefits of the proposed research project, (b) determine if the research design is capable of answering the research questions, and (c) ensure that the research procedures and materials conform to established ethical standards.
Delegated Review
Where a proposal: (a) poses only minimal risk, (b) has been approved elsewhere by a Tri-Council policy-compliant REB, and/or (c) 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, the REB will assign two (2) members to review the proposal and its conformity to established research ethics standards and practices.

To undergo REB review, researchers will submit to the REB, in addition to the *Request for Ethics Review (Form 1)*, the following documentation:

a. The research proposal, in sufficient detail to permit the REB to make an assessment of its ethical acceptability;

b. Experimental protocol (where appropriate);

c. Informed consent statement and forms (as necessary: normally, participants must also be given a copy of the informed consent form which they have signed);

d. Copies of questionnaires and research instruments (where appropriate);

e. Evidence of TCPS 2-CORE completion or equivalent research ethics training;

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

C. Research Ethics Board

6. Mandate

a. The REB is responsible for reviewing the ethical acceptability of all research conducted within the jurisdiction of VCC or under its auspices that involves human participants: its role is to educate researchers and to review and monitor research proposals and projects. It conducts independent multidisciplinary review of research proposals to determine if they meet ethical requirements necessary for initiation or annual continuance.

b. The REB serves as a consultative body on research ethics and assists in educating the VCC community about research ethics.

7. Authority of the Research Ethics Board

a. The College mandates the REB to approve, reject, and propose modifications to or termination of 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 Policy as a minimum standard.

b. The REB is an independent standing committee with terms of reference approved by the Board of Governors. The REB's decision to approve or deny proposals for research is made independently and may not be set aside without formal appeal.

8. Membership of the Research Ethics Board

a. The REB shall consist of at least five (5) members, including both men and women, of whom:

i. 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;

ii. at least one (1) member is knowledgeable in ethics;

iii. for biomedical research, at least one (1) member is knowledgeable in the relevant law; and

iv. at least one (1) member has no affiliation with the College, recruited from the community served by the institution.

Each member should be appointed to fulfill the formal requirements of a single category.

b. The REB may from time to time also call on specialists to advise on particular proposals that require additional expertise for appropriate review.

c. The REB will elect a Chair each year from among its membership. The position is renewable.

9. Meetings and Attendance

a. The REB will meet regularly and as needed to review requests and carry out REB business. It is preferred for members to attend and participate in face-to-face meetings.

b. A quorum for committee purposes for a full review is at least four (4) members, 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.

10. Record Keeping

    a. Minutes of all VCC-REB meetings shall be prepared and maintained by the chair or designate. The minutes shall 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.

    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.

    c. The required records will be retained for three (3) years, and records relating to research that is conducted will be retained for at least three (3) years after completion of the research.

11. Decision Making

    a. 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 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 (within five to eight weeks) 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 four [4] members present, plus the chair) will be adopted only if the members attending the meeting possess the relevant competence and knowledge necessary to review the proposals under consideration.

    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 or delegate 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. Reject the proposed research activity.

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

12. Reconsideration

    a. 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 its 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.

13. Appeals

    If a request for a review is unsuccessful in resolving the disagreement, the researcher has the right to a formal appeal of the REB's decision to the Vice President, Academic & Research (VPAR). Upon application by a researcher for a formal appeal of a REB decision, the VPAR shall refer the matter to an appeal committee; the VPAR may either refer the matter to an appeal committee at another institution or may establish a special Research Ethics Appeal committee to hear the appeal. In either case, no member of the REB whose decision is being appealed may be a member of the committee that hears the appeal. If the matter is referred to another institution for review, that institution must have a Research Ethics Policy and Board whose operations are compliant with the *Tri-Council Policy Statement*, and VCC must have a prior agreement in place with that institution to refer appeals under this policy. In either case, the decision of the appeal committee shall be final.

14. Conflicts of Interest

    a. 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.

    b. Disclosure of conflicts of interest will comply with the VCC's Conflict of Interest in Research policy (F.1.03).

15. Review of Multi-Centered Research
    REB is responsible for the ethical acceptability of research undertaken within VCC's jurisdiction or under its auspices. In case of any ethical concerns, when local practices or standards in other jurisdiction vary from those of VCC, VCC's REB will require its researchers to comply with whichever expectations are more rigorous.

Section 2: Free and Informed Consent

A. Requirement for Free and Informed Consent

16. Research governed by this Policy may begin only if (a) prospective participants, or authorized third parties, have been given the opportunity to give free and informed consent voluntarily (i.e., without manipulation, undue influence, or coercion) about

participation, and (b) their free and informed consent has been given and is maintained throughout their participation in the research.

17. Evidence of free and informed consent by the subject 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.

18. 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 have an adverse effect on welfare of the participants;

    c. The research could not practicably be carried out without the waiver or alterations;

    d. In the case of a proposed alteration, the nature and extent of the alteration is clearly defined. Wherever possible and appropriate, a plan to provide debriefing to participants and the opportunity to refuse consent and/or withdraw data and/or biological materials.

B. Special Considerations Regarding Consent

19. In some *randomized* and/or *blind clinical trials*, neither the research participants nor the researchers know which treatment the participants are receiving. Random/blind assignment is not regarded as an alteration of consent requirements if the participants are informed of the probability of being randomly assigned.

20. Some social science research requires the use of *partial disclosure* or *deception* (e.g., giving participants false information about themselves, events, social conditions, the purpose of the research); for such techniques to be considered an exception to the general requirement of full disclosure for consent, the research must meet all the REB waiver/alteration requirements.

21. In some population and public health research, prior informed consent is not obtainable as communicating with community members through a consent process could affect the group response: in such cases, researchers must explain clearly why the research question cannot be answered without an exception to the requirement of prior consent and, if possible, seek community engagement prior to data collection.

22. An individual medical emergency, where an individual who requires urgent medical care is unable to provide consent for research due to unconsciousness or a loss of decision-making ability, is subject to special exemption from informed consent requirements because certain medical emergency practices can be applied only when such emergencies occur. The REB may allow research that involves medical emergencies to be carried out without participants' informed consent if all of the following apply:

a. There is a serious threat to the prospective participant that requires immediate intervention;

b. The research offers the best or only option for treatment;

c. The risk of the research treatment is clearly justified by the prospect of the direct benefits to the participant;

d. The participant is not conscious or otherwise able to make an informed consent decision;

e. Third-party authorization cannot be secured in sufficient time, despite due diligence; and

f. No relevant prior directive by the participant is known.

When a previously incapacitated participant regains decision-making ability or third-party authorization is found, consent shall be sought promptly for any continuing or subsequent treatment related to the research.

23. Whether or not consent is required for research involving *naturalistic observation* depends on the degree of privacy expected by individuals in a given setting, the nature of the research, and the potential to violate sensitive interests. Purely observational research done in public settings where there is no expectation of privacy is exempt from REB review; however, some material that is publicly accessible may still require participants' consent due to the expectation of privacy attached to certain groups or activities (e.g., religious/cultural ceremonies, online chatroom discussions).

C. Informing Potential Participants

24. General Conditions
Researchers shall provide, to prospective participants or authorized third parties, full and frank disclosure of all information relevant to voluntary, informed, and ongoing consent. Throughout the consent process, the researcher must ensure that prospective participants are given adequate opportunities to discuss and contemplate their participation. The REB may approve research without requiring that the researcher obtain participants' consent where the REB is satisfied that all of the following apply:

a. Information that the individual is being invited to participate in a research project;

b. A comprehensible statement of the research purpose, the identity of the researcher(s), the expected duration and nature of participation, and a description of research procedures;

c. A comprehensible description of reasonably foreseeable harms and benefits that may arise from research participation, as well as the likely consequences of non-action, particularly in research related to treatment, or where invasive methodologies are involved, or where there is a potential for physical or psychological harm;

d. An assurance that prospective participants are free not to participate, have the right to withdraw at any time without prejudice to pre-existing entitlements,

and will be given continuing and meaningful opportunities for deciding whether or not to continue to participate.

D. Decision-Making Capacity

25. Subject to applicable legal and regulatory requirements, individuals who lack the ability, either permanently or temporarily, to decide for themselves whether or not to participate, the REB shall ensure that, as a minimum, the following conditions are met:

    a. The researcher involves the participants in the decision-making process to the greatest extent possible;

    b. The researcher seeks and maintains consent from authorized third parties who have the participants' best interests in mind;

    c. The authorized third party may not be the researcher or any other member of the research team;

    d. The researcher demonstrates that the research is being done for the participants' direct benefit or the benefit of others in the same category; in the latter situation, the researcher shall demonstrate the research will pose only minimal risk and burden to the participant;

    e. When participation in a research project occurred through third-party authorization, and a participant regains decision-making ability during the course of the project, the participant's informed consent shall be sought as a condition of continuing participation.

RELATED POLICIES

Refer to F.1.1 Ethical Conduct for Research Involving Humans Policy