KPU | KWANTLEN POLYTECHNIC UNIVERSITY

Policy History
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Approving Jurisdiction: President
Administrative Responsibility: Provost and Vice President Academic
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Research Involving Human Participants Procedure

DEFINITIONS

Authorized Third Party
A person with the necessary legal authority to make decisions on behalf of an individual who lacks the capacity to consent to participate or to continue to participate in a particular research project.

Human Participant
An individual whose data, or responses to interventions, stimuli, or questions by a researcher are relevant to answering a research question.

Minimal Risk
Research in which the probability and magnitude of possible 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.

Principal Investigator
The researcher who has primary responsibility for a given research project. Every project has one investigator designated as the Principal Investigator. With the exception of course-based research (as described below), the instructor advising a student engaged in a research project (including a practicum assignment that involves research, a major project or thesis) shall function as the principal investigator for the purposes of obtaining ethical approval and complying with the requirements of this Policy.

Research
For the purposes of this Policy, "research" is defined as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation. This Policy applies to all Kwantlen research which involves humans as research participants (formerly referenced as "subjects").

This includes most naturalistic observation, physical, sociological or psychological tests and measurements, survey research, non-intrusive systematic observation, and the study of recorded data from previous studies, databases and archives, in which it is possible to identify living individuals. This also includes human remains, cadavers, human organs, tissues and biological fluids from individually identified participants, embryos or fetuses.

GUIDELINES

A. ROLE AND RESPONSIBILITIES

1. The Vice President Academic has designated the Associate Vice President, Research as the administrator responsible.
2. The administrator responsible shall establish and maintain a Research Ethics Board (REB) to help ensure that ethical principles are applied to research involving human participants. The Associate Vice President, Research shall provide appropriate institutional administrative support to the REB and the Office of Research Ethics.

3. The REB is charged by the President with the responsibility of ensuring that Kwantlen's ethical principles are followed when research involves human participants. When it performs this function, the REB is doing so as the designated agent of the President.

4. The principal decision-making responsibilities of the REB are:

    a. Approving a research proposal that complies with the above ethical principles, rejecting a research proposal that does not comply, proposing modifications to a research proposal in order to bring it into compliance, or rescinding approval of ongoing research that ceases to be in compliance.

    b. Consulting as it deems necessary with experts who are not members of the committee in order to make an informed judgment on the ethical principles as they apply to an individual research proposal

5. The REB shall meet regularly (normally monthly) to discharge its responsibilities. Reviews of proposed research that is not subject to delegated review shall be face-to-face and shall be based upon fully detailed research proposals or, where applicable, progress reports. Videoconferencing, teleconferencing or use of other technologies may be regarded as meeting the face-to-face requirement when there is no other way of holding an effective, quorate REB meeting.

6. In collaboration with the Associate Vice President, Research, the REB shall recommend, develop and implement research ethics educational opportunities for researchers. Individual researchers may consult with the REB Chair for advice on preparation of applications and the REB Chair may seek the advice of other REB members in providing this advice. All formal communication with the REB shall be via the REB Chair in order to maintain a clear, consistent record.

7. All researchers, including students engaged in course-based research, shall successfully complete the Tri-Council on-line tutorial accessed at http://www.pre.ethics.gc.ca/english/tutorial, or a similar tutorial approved by the REB prior to commencement of their research involving humans.

8. The REB may collaborate with other REBs on the review of multi-centred projects, and may communicate any concerns they have with the other REBs reviewing the same project.

9. It is not the responsibility of the REB to determine whether or not research activities described in a research proposal:

    a. Conflict with the law of British Columbia or Canada or another jurisdiction where the research is proposed to be conducted except to the extent that it may be necessary for the REB to determine whether or not the proposed research methodology satisfies Kwantlen's ethical principles and policies; or
    b. Subject Kwantlen to an unacceptable risk of legal liability for a claim for compensation for harm, loss or damage caused by the research activities.

10. Conflict with the law and legal risk which does not directly impact ethical considerations may be assessed by the Associate Vice President, Research.

B. MEMBERSHIP

1. The REB shall consist of at least five voting members, including both men and women, of whom

    a. at least two members have broad expertise in the methods, or in the areas of research that are covered by the REB,
    b. at least one member is knowledgeable in ethics,
    c. at least one member has no affiliation with the institution, but is recruited from the community served by the institution. In addition to a broad-based representation from the community, it is highly desirable to appoint one or more former research participants.

    Where possible, one member will additionally have legal knowledge. For consideration of biomedical research, at least one member shall be knowledgeable in the relevant law; if no regular member meets that criterion, a member may be appointed ad hoc for consideration of that research, as per section 3 below. The Office of Research and Scholarship shall maintain general records related to REB membership and qualifications of members (*e.g.*, copies of curriculum vitae, participation in relevant research ethics training). To ensure the independence of REB decision making, Kwantlen senior administrators shall not serve on the REB.

2. The REB Chair is a voting member of the REB.

3. The REB Chair may, in consultation with the Associate Vice President, Research, supplement the REB with one or more *ad hoc* members to review a specific project where it is deemed that expertise is lacking among regular REB members.

4. Members of the REB will normally serve for two-year terms. An annual, staggered system of selection will be employed. Members can be selected for consecutive terms. Normally, no more than two consecutive terms will be served. Terms will begin and end according to the academic year.

5. No later than five months prior to the start of the academic year, the Associate Vice President, Research will inform the Kwantlen community of the need for new members and of the areas of expertise to be filled on the REB and will solicit nominations and applications.

6. After receiving the nominations and applications, the Associate Vice President, Research will review them with the REB. The REB will make recommendations of individuals to serve. The Associate Vice President, Research will then present those recommendations and his/her own, if they differ, to the President.

7. The President shall then appoint the new REB members.

8. All members of the REB shall be knowledgeable about the principles and practices of ethical review of research. REB members may complete the on-line tutorial accessed at http://www.pre.ethics.gc.ca/english/tutorial or a similar tutorial approved by the REB, if they do not already meet this requirement.

9. Regular attendance by REB members at meetings is required. More than one unexplained absence will be construed as a notice of resignation.

10. The members of the REB shall annually elect a Chair from among their number.

11. If the REB is unable to elect a Chair from among their number, the Associate Vice President, Research will recommend one or more candidates to the President and the President shall appoint a Chair. The candidates recommended by the Associate Vice President, Research may be present REB members, other Kwantlen employees or, in exceptional circumstances, individuals external to Kwantlen.

12. The Associate Vice President, Research, with approval of the Chair of the REB, shall appoint additional members in order to replace regular members who resign during their term or who are have been absent (and construed to have resigned as per section 9 above). This appointment shall occur within two months of the resignation and maintain the required balance of expertise on the REB. Members appointed in this way will serve for the remainder of the original term of the member they replace. They may be considered under the regular process described above for subsequent terms

13. . If the Chair is temporarily unable to perform his/her duties, the Associate Vice President, Research shall be informed and the REB shall elect one from among their number to serve as Chair *pro tem* for the purpose of chairing the REB meeting.

C. INDEPENDENCE OF REB

1. Consistent with TCPS requirements, Kwantlen respects the authority delegated to the REB to make final determinations concerning the ethical probity of research proposals and research undertaken under its auspices.

2. A decision of the REB that a research proposal satisfies Kwantlen's ethical principles does not necessarily mean that a research project may proceed or continue. Consistent with the TCPS, Kwantlen senior administration may refuse to allow certain research under its auspices, even though the REB has found it acceptable ethically.

D. REQUIREMENT FOR FREE, INFORMED AND CONTINUING CONSENT

1. Research governed by this Policy may begin only if

    a. prospective participants, or their authorized third parties, have been given the opportunity to give free and informed consent about participation, and
    b. their free and informed consent has been given and is maintained throughout their participation in the research, except as provided in Sections 3 and 6 below.

2. Evidence of free and informed consent by the 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. Reference to TCPS Chapter 10 on Qualitative Research may be helpful.

3. The REB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent (permitting, for example, partial disclosure or deception) 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 a debriefing and additional pertinent information after participation; and
    e. The waived or altered consent does not involve a therapeutic intervention.

4. Provided that participants are informed of the probability of being randomly assigned to one arm of a study or another, a waiver or alteration of the requirements for consent is not required in studies which involve randomization and blinding, as neither the research participants nor those responsible for their care know which arm of the study the participants are in before the project commences.

5. Free and informed consent must be voluntarily given, without manipulation, undue influence or coercion.

6. Researchers shall provide, to prospective participants and to authorized third parties, full disclosure of all information necessary for making an informed decision to participate in a research project.

    a. 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 the listed elements are required for all research. However, additional information may be required in particular types of research or under particular circumstances.

b. If a researcher does not include some of the listed disclosure requirements, he or she should explain to the REB why these requirements do not apply to that particular project. It is also up to the REB to decide whether all elements listed, or additional elements, are necessary to the consent process of the research project. The information generally required for informed consent includes:
c. information that the individual is being invited to participate in a research project;
d. a statement of the research purpose in plain language, 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;
e. a plain language description of all reasonably foreseeable risks and potential benefits, both to the participants and in general, that may arise from research participation;
f. an assurance that prospective participants:

    i. are under no obligation to participate; are free to withdraw at any time without prejudice to pre-existing entitlements;
    ii. 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
    iii. will be given information on the participant's right to request the withdrawal of data or human biological materials, including any limitations on the feasibility of that withdrawal;

g. 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 the researchers, their institutions or the research sponsors;
h. description of the measures to be undertaken for dissemination of research results and whether participants will be identified directly or indirectly;
i. the identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the research to participants;
j. 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;
k. indication of what information will be collected about participants and for what purposes; 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;
l. information about any payments, including incentives for participants, reimbursement for participation-related expenses and compensation for injury;
m. 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
n. in clinical trials, information on stopping rules and when researchers may remove participants from the trial.

7. Capacity refers to the ability of prospective or actual participants to understand relevant information presented about a research project and to appreciate the potential consequences of their decision to participate or not participate. Absence of such capacity may stem from any of a number of factors including (but not limited to) immaturity,

cognitive impairment, other mental health issues, or illness. Assessing capacity is a matter of determining, at a particular point in time, whether a participant or prospective participant sufficiently understands the nature of the research project and the risks, consequences and potential benefits associated with it.

a. 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:
b. the researcher involves participants, who lack the capacity to consent on their own behalf to the greatest extent possible, in the decision-making process;
c. the researcher seeks and maintains consent from authorized third parties in accordance with the best interests of the persons concerned;
d. the researcher ensures that authorized third parties who are asked to make a consent decision on behalf of a prospective participant are aware of their legal responsibilities;
e. the authorized third party is not the researcher or any other member of the research team;
f. 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;
g. 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
h. when authorization for participation was (is?) granted by an authorized third party, and a participant acquires or regains capacity during the course of the research, the researcher shall promptly seek the participant's consent as a condition of continuing participation.

8. Where an authorized third party has consented on behalf of an individual who lacks capacity to consent, but that person has the ability to understand the significance of the research and its risks and benefits, the researcher shall ascertain the wishes of that individual with respect to participation. Prospective participants' dissent will preclude their participation.

9. In the cases of prospective participants who are under the age of legal majority in British Columbia (19), for the purposes of this Policy:

    a. Individuals 16 to 18 years of age will normally be deemed to have the capacity to give their free and informed consent to participate in minimal risk research;
    b. Research exceeding minimal risk involving individuals 16 to 18 years of age will be considered by the REB on a case-by-case basis to determine whether the free and informed consent of their authorized third parties will be required. Decision criteria may include the nature of the risks and the identifiability of their authorized third parties.
    c. Individuals 14 to 15 years of age may be deemed to have the capacity to give their free and informed consent to participate in minimal risk research; this will be determined by the REB on a case-by-case basis;
    d. Research exceeding minimal risk involving individuals 14 to 15 years of age will normally require the free and informed consent of their authorized third parties;
    e. Persons under the age of 14 may not participate as research participants in either

minimal or non-minimal-risk research protocols without the free and informed consent of their authorized third parties.

10. Kwantlen researchers planning research involving clinical trials of drugs or medical devices should consult chapter 11 of the TCPS for detailed information on acceptable procedures to follow.

11. Kwantlen researchers do not currently conduct research involving emergency health situations. Policy addressing the special circumstances surrounding free and informed consent in these circumstances will be developed before research may be undertaken in this area.

E. REVIEW PROCESS

1. Application for Ethics Review

    a. The principal investigator is responsible for submitting research proposals to the REB for review prior to initiating the research. The use of Form #8 "Application for Ethics Review", found on the Kwantlen REB website, is required and must be completed and submitted electronically (hand-written forms will not be accepted). It is the responsibility of the principal investigator to ensure that the research is carried out ethically, including the need to incorporate the principles of free and informed consent, privacy and confidentiality, conflict of interest, and the needs of specific populations of research participants. This also entails following the approved protocol and abiding by the decision of the REB if the project is not approved.
    b. A Kwantlen instructor enrolled in a graduate program at another institution or otherwise conducting research approved by an REB at another institution, if that research is to be conducted under Kwantlen's auspices, shall seek and obtain the approval of the Kwantlen REB. The use of Form #13 "Application for Ethics Review, Expedited Review of Minimal Risk Project Approved at Another Research Institution", found on the Kwantlen REB website, is required for minimal risk research and the use of Form #8 is required for other research.
    c. Prior to Kwantlen REB review, researchers who plan research involving First Nations, Inuit and Métis peoples, regardless of where they reside and whether or not 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 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.
    d. A researcher presenting a proposal for multi-jurisdictional research – research which involves Kwantlen and sites overseen by other REBs – must identify the research as such, and provide the Kwantlen REB with contact information for all REBs with potential

oversight. The researcher may consider providing the REBs with detailed information concerning core elements of the research – which cannot be altered without invalidating the pooling of data from the participating institutions – and those elements which can be altered to comply with local requirements without invalidating the research project. Kwantlen's REB may coordinate their review of such projects with other REBs, including sharing information and concerns with the other REBs during the review process.

e. Research to be performed outside of Canada shall undergo prospective ethics review both by Kwantlen's REB and 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.
f. As part of an application submitted for REB review, researchers shall disclose to the REB any real, potential or perceived individual conflicts of interest, as well as any institutional conflicts of interest of which they are aware that may have an impact on their research. The REB shall determine the appropriate steps to manage the conflict of interest. This may require disclosure of all kinds and amounts of contributions (financial or in-kind) to the researchers by sponsors, commercial interests, and consultative or other relationships, as well as any other relevant information that may affect the project (*e.g.*, donation to the institution by a research sponsor). The REB may require access to the complete budget for the project.

2. Review

a. The REB shall function impartially and provide reasoned and appropriately documented decisions.
b. REB decisions should normally be by consensus. In the event of a tied vote, the Chair's vote becomes the deciding vote.
c. A quorum shall consist of four voting members, where those members meet the minimum requirements of representation outlined in section B 1.
d. When there is less than full attendance, decisions requiring full review shall be adopted only when the members in attendance at that meeting have the specific expertise, relevant competence and knowledge necessary to provide an adequate research ethics review of the proposal(s) under consideration.
e. The purpose of scholarly review is to elucidate whether the research project (1) adheres to established, high scholarly standards stipulated by the relevant discipline; (2) is capable of addressing the questions being asked in the research; and (3) will further the understanding of the phenomenon or issue in question.
    i. Scholarly review will not normally be required when the research is at most minimal risk.
    ii. It is the REB's responsibility to ensure that an appropriate process of scholarly review and approval has been completed for each research project that requires full review.
    iii. It is normally the researcher's responsibility to document the scholarly review and approval, if required by the REB.
    iv. If scholarly review as indicated and there is nobody available to perform it, the REB shall consider the following mechanisms in satisfying itself that scholarly review of the research is completed:
        1. if the REB itself has the necessary scholarly expertise, assume responsibility for the scholarly review; or

2. establish an *ad hoc* independent peer review committee.

f. When reviewing research in which a member of the REB has a personal interest (*e.g.*, as a researcher, recent collaborator or as an entrepreneur), conflict of interest principles require that the member not be present when the REB is discussing the proposal 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 disclosed to the REB. The principal investigator, if not the REB member, has the right to hear the evidence of conflict and to offer a rebuttal.
g. Decisions of the REB to approve, modify, or reject a research proposal or to rescind approval for ongoing research are filed with the Office of Research Ethics, together with a copy of the research proposal, any conditions imposed by the REB, and the Chair's notice to the researcher.
h. Minutes of meetings of the REB are filed with the Office of Research Ethics. The minutes shall clearly document the REB's decisions, any dissents and the reasons for them. In order to assist internal and external audits or research monitoring, and to facilitate reconsideration or appeals, these records must be accessible to authorized representatives of the institution and research funding agencies.
i. The REB Chair shall send an annual report summarizing the activities of the REB to the Associate Vice President, Research whom shall then send it to the President.

3. Notification

a. In the case of approval of a proposed project, written notice of ethics approval ("Ethics Certificate") will be sent to the principal investigator by the Chair of the REB.
b. In the case of rejection or when more information is required before the submission can be finally considered, the Chair of the REB will communicate in writing with the principal investigator. The Chair shall provide the principal investigator with a rationale for the REB's decision or request.
c. Public notices (posters, emails, etc.) soliciting participation in the research shall contain reference to the approval of the project by the Kwantlen REB and the project number assigned by the Office of Research Ethics.

4. Delegated REB review

a. This is the level of REB review assigned to minimal risk research projects. A delegated reviewer may be the REB Chair or may be selected by the Chair from among the REB membership. Approvals made under the delegated review process must be reported to the next REB meeting with a brief rationale for the decision. If the delegated reviewer is not able to approve the proposal, it will be referred to the full REB at its next meeting for decision.

5. Delegated review of course-based research

    a. Ethical review of course-based research by students may be performed by delegates from the student's Department, Faculty, or an equivalent level, as described below.
    b. Course-based research occurs within the context of a specific course offering, and involves an assigned research activity, the key objective of which is to allow students to learn about the research process. When course-based research involves human participants, it falls within the scope of this Policy.
    c. Instructors of courses that include course-based research must submit to the REB for approval, prior to commencement of the course-based research, Kwantlen REB Form #6, "Application for Approval of Minimal Risk, Course-Based Research", found on the Kwantlen REB website, accompanied by the following:
        i. the official current, approved course outline,
        ii. a description of the types of student research that will be undertaken,
        iii. a description of the methods by which the ethical standards are taught to students; the minimum requirement is successful completion of the TCPS Tutorial, accessed at http://www.pre.ethics.gc.ca/english/tutorial, or a similar tutorial approved by the REB,
        iv. templates on which students present their proposed research, including the free and informed consent protocol,
        v. a description of the methods by which research proposals and informed consent protocols are to be assessed by the instructor,
        vi. evidence that the instructor has completed the on-line TCPS Tutorial (see above), or a similar tutorial approved by the REB, and
        vii. a signed confirmation that all student research will be of minimal risk to the participants and will conform to TCPS ethical principles and the principles incorporated in this Policy. Specifically: instructors should ensure that all materials related to their students' research (*e.g.* signed consent forms, data, questionnaires) are handled in manners consistent with this Policy.
    d. Instructors must re-submit a request for approval whenever there are material changes planned in any of the elements listed above. Re-submission will be required when the official course outline is reviewed according to the normal review schedule, if there are any material changes.
    e. Extension of approval to a new instructor requires submission of the form "Course-Based Research Extension of Approval" found on the Kwantlen REB website.
    f. 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, or
        ii. course-based research by students which is above minimal risk, or
        iii. research which forms a component of an instructor's own research.
    g. In these cases, the instructor must submit an application for full or delegated review as appropriate and shall function as the principal investigator for the purposes of obtaining ethical approval and complying with REB requirements.

F. RECONSIDERATION AND APPEAL

1. Applicants have the right to appeal negative decisions of the REB. An appeal can be launched

for procedural and/or substantive reasons.

2. Where the appeal concerns on-going research, the REB may direct that the research be suspended during the Consultative Dialogue and Formal Appeal period(s).

3. Consultative Dialogue (initial appeal)

    a. Before initiating a Formal Appeal of a decision to reject a proposal or to stop research previously approved by the REB, the principal investigator must submit to the REB a written request for reconsideration, with rationale. If the written request is not approved by the REB, the REB shall meet with the principal investigator to reconsider its decision.
    b. The results of the REB's reconsideration will be conveyed to the principal investigator in written form, with the rationale for its decision provided.

4. Formal Appeal

    a. Kwantlen shall enter into an agreement with an institution, whose Human Research Ethics Board shall function as an Appeal Board for the purposes outlined in this Policy. In return for providing the Appeal Board, the Kwantlen REB may be made available to hear appeals of applications rejected by the REB of the other institution. Currently, Kwantlen has a Memorandum of Understanding (MOU) to this effect with the University of the Fraser Valley.
    b. A principal investigator wishing to formally appeal a decision of the Kwantlen REB to reject a research proposal or to rescind approval of on-going research (the Appellant) must engage in the consultative dialogue process described above. Within 30 days of receipt of notification of the REB's decision following its reconsideration, the Appellant shall provide the Associate Vice President, Research with the following:
        i. the final application, as submitted to the Kwantlen 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 Associate Vice President, Research the REB materials specified in the MOU.
    d. The Associate Vice President, Research shall submit all the materials to the Appeal Board within five working days of receipt of the materials described above.
    e. Decisions of the Appeal Board shall be final and binding upon Kwantlen and the Appellant.

G. POST-APPROVAL MONITORING

1. The REB will maintain continuing oversight of the research after the project has received initial ethical approval.

2. In the conduct of their approved research, should unanticipated issues arise that may increase the level of risk or have other ethical implications, researchers shall report them to the REB in a timely manner.

3. If a change in the research procedures is contemplated, the principal investigator will immediately submit an amended proposal to the REB for review. The amended proposal should consist of the original application with changes high-lighted and a cover page on which the changes are summarized. The REB Chair will be available for advice.

4. Ongoing research is subject to continuing ethics review. The rigour of the continuing review will be in accordance with a proportionate approach to ethics assessment. Research that poses greater-than-minimal risk may require more extensive continuing ethics review. This may include more frequent reporting to the REB, monitoring and review of the consent process, review of participant records, and site visits.

5. An on-going status report on the research must be submitted to the REB by the principal investigator annually, or more frequently, as required by the REB. This includes summary reports by the course instructor on course-based research of the students in the course.

6. In addition to the above requirement, the REB may work with the researcher to develop an appropriate plan for continuing review and the reporting structure for the termination of the project. Some examples of continuing review processes include:

    a. formal review of the process of free and informed consent;
    b. establishment of a safety monitoring committee;
    c. periodic review by a third party of the documents generated by the study;
    d. review of reports of adverse events;
    e. review of patients' charts;
    f. random audit of the process of free and informed consent; and
    g. random audit of the implementation of the approved research protocol.

7. Kwantlen has no institutional policy on retention of research data or consent forms. Appropriate retention periods vary depending on the research discipline, research purpose and the kind of data involved. Some funding bodies, such as the Social Sciences and Humanities Research Council and the Canadian Institutes of Health Research, have specific policies on data archiving and sharing. Researchers are reminded that the use of information for purposes other than that originally approved is not permitted, with the exception of data that are fully anonymous and the process of data linkage or recording or dissemination of results does not generate identifiable information about the participants whose information is included.

8. 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.

H. BREACH OF POLICY

1. Kwantlen reserves the right to immediately halt any research involving human participants that has been started without the required approval, or which does not follow the approved protocol.

2. Kwantlen employees may be served with a warning letter and/or lose research privileges and funding for serious or repeated violations of ethics policy. Existing disciplinary processes may also apply. For students, penalties may include a warning letter, a failing grade on a research project, or suspension from studies and will be dealt with under the existing academic disciplinary process.

I. EXEMPTIONS FROM ETHICS REVIEW

The following activities do not require approval by the REB, but researchers must consult, prior to initiating the project, with the REB if there is uncertainty as to whether a project constitutes research or requires approval from the REB.

1. Research that relies exclusively on publicly available information does not require REB review 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.

2. Interactions with individuals, who themselves are not the focus of the research, only in order to obtain information about their organizations. For example, one may collect information from authorized individuals, in the ordinary course of their employment, about the employing organization, its policies, procedures, professional practices or statistical reports. Such individuals are not considered research participants for the purposes of this Policy.

3. Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this Policy, and do not fall within the scope of REB review.

4. REB review is not required for research involving the observation of people in public places where:

    a. it does not involve any 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.

5. REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information.

RELATED POLICY

Refer to RS1 *Research Involving Human Participants Policy*