KPU | KWANTLEN POLYTECHNIC UNIVERSITY

| Policy History |
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| **Policy No.** RS1 |
| **Approving Jurisdiction:** President |
| **Administrative Responsibility:** Provost and Vice President Academic |
| **Effective Date:** April 10, 2012 |

# Research Involving Human Participants Procedure

This version is valid until December 30, 2025.
*See Section 2 for version effective on January 1, 2026.*

# 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*

KWANTLEN POLYTECHNIC UNIVERSITY

| Policy History |
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| **Policy No.**<br>RS1 |
| **Approving Jurisdiction:**<br>Board of Governors |
| **Administrative Responsibility:**<br>Provost and Vice President Academic |
| **Effective Date:**<br>January 1, 2026 |

# Research Involving Humans Procedure

## A. DEFINITIONS

1. **Administrative Approvals:** Administrative approvals refer to the other institutional approvals needed for a research project beyond ethical approval from the Research Ethics Board (REB) for research involving humans). These approvals generally follow from university policies and other legal obligations and commitments.

2. **Amendment:** A request submitted to the REB by researchers to modify an already approved research project proposing changes that affects the ethical acceptability of research. Amendments may involve proposed modifications to the study's protocol, procedures, consent forms, recruitment methods, study personnel, or other elements that may affect the ethical acceptability of the research.

3. **Application or Research Ethics Application:** A request submitted by a researcher to the REB (for ethical consideration in accordance with the TCPS) that sufficiently delineates the goals, methodology, risks, and benefits of a proposed research study involving humans.

4. **Appeal:** A process that allows a researcher to request a review of a REB decision when, after reconsideration, the REB has refused ethics approval of the research (adapted from Glossary, TCPS).

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| **5.** | **Appeal Board or Research Ethics Appeals Board:** | A body designated by KPU to review appeals from researchers of decisions made by a REB. This board functions as an independent, impartial body composed of individuals with the relevant expertise to assess appeals fairly.<br><br>Note: At this time, KPU has an agreement with the University of the Fraser Valley whereby the REB of each university serves as the Appeal Board for appeals originating from the other university. |
| **6.** | **Community-Based Research:** | A research approach that involves active participation of stakeholders, those whose lives are effected by the issue being studied, in all phases of research for the purpose of producing useful results to make positive changes (as used by Community Based Research Canada[1]) |
| **7.** | **Continuing Research Ethics Review:** | Any review of ongoing research conducted by a REB occurring after the date of initial REB approval and continuing throughout the life of the project to ensure that all stages of a research project are ethically acceptable in accordance with the principles in the Policy (adapted from Glossary, TCPS). |
| **8.** | **Core Principles:** | The four core principles that together express the overarching value of respect for human dignity: Respect for Persons, Concerns for Welfare, and Justice (per Article 1.1, TCPS) as well as Cultural Safety and Respect for Indigenous Peoples. |
| **9.** | **Delegated REB Review:** | The level of REB review generally assigned to minimal risk research projects. |
| **10.** | **Data Management Plan(s):** | Data management plans (DMPs) are living documents that outline a project team's plans for research data management (RDM) during a research project and for its long-term storage. DMPs describe:<br><br>• how data will be collected, documented, formatted, protected and preserved; |

[1] adapted from Nelson, Ochocka, Griffin & Lord, 1998, p2 "Nothing about me without me": Participatory action research with self-help/mutual aid organizations for psychiatric consumers/survivors. American Journal of Community Psychology, 26, 881-912)

- how existing datasets will be used and what new data will be created over the course of the research project;
- whether and how data will be shared; and
- where data will be deposited.

DMPs also indicate who is responsible for managing the project's data, describe the succession plans in place should that person leave the research team, and identify the data-related roles and responsibilities of other team members where appropriate. Finally, DMPs outline ethical, legal and commercial constraints the data are subject to, and methodological considerations that support or preclude data sharing (adapted from Tri-Agency RDM policy).

**11.** **Duty of Care:** In this context, refers to the ethical and legal obligation of researchers and the institution to ensure the safety, well-being, and rights of research participants. Specifically, researchers must act with diligence, fairness, and integrity, taking all reasonable steps to prevent harm and uphold the highest standards of responsible research conduct. This duty extends across various dimensions, including physical, psychological, and informational protections (from the Office of General Counsel).

**12.** **Ethics Approval:** An approval of an application to conduct a specified research project involving humans, granted by the REB in accordance with this policy, confirming that the proposed study adheres to the ethical principles defined in the TCPS and in this policy.

**13.** **Equity-Denied:** Refers to individuals who are historically disadvantaged and underrepresented due to systemic inequities or biases based on race, gender, socioeconomic status, disability, sexual orientation, or other characteristics. (adapted from Glossary: Canadian Center for Diversity and Inclusion).

**14.** **Full REB Review:** The level of REB review assigned to above minimal risk research projects. Conducted by the full membership of the REB, it is the default requirement for the ethics review of research involving humans (adapted from Glossary, TCPS).

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| **15.** | **Guidance Documents:** | Developed by the REB, guidance documents are designed to support researchers (and the REB) in interpreting the TCPS and navigating research ethics considerations and related processes at KPU. They may include position statements, interpretive guidelines, or related documents. |
| **16.** | **Guidelines:** | Administrative documents developed by the Office of Research Services to interpret and implement the university's policies by providing practical direction**,** procedural clarity**,** and tools to help researchers, administrators, and oversight bodies in day-to-day practice. These may include process steps, timelines, and forms. |
| **17.** | **Human Biological Materials:** | This refers to tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva, and other body fluids. The term also includes materials related to human reproduction, including embryos, fetuses, fetal tissues and human reproductive materials (adapted from Glossary, TCPS). |
| **18.** | **Human Genetic Research:** | The study of genetic factors responsible for human traits and the interaction of those factors with each other, and with the environment (adapted from Glossary, TCPS). |
| **19.** | **Incident Reporting Form:** | A formal document from the REB for researchers to report any unanticipated incident occurring while carrying out a REB-approved study. These events may arise during or after data collection, leading to a greater risk of harm (physical, psychological, economic, or social) to participants than was previously anticipated. |
| **20.** | **Indigenous Peoples:** | In Canada, the term "Indigenous peoples" refers to persons of First Nations, Inuit, or Métis descent, regardless of where they reside and whether their names appear on an official register. In Canada, a comparable term, "Aboriginal peoples" is also used in certain contexts (adapted from Glossary, TCPS). |
| **21.** | **Indigenous Research:** | Research in any field or discipline that is conducted by, grounded in or engaged with First Nations, Inuit, Métis or other Indigenous nations, communities, societies or individuals, and their wisdom, cultures, experiences or |

knowledge systems, as expressed in their dynamic forms, past and present. Indigenous research can embrace the intellectual, physical, emotional and/or spiritual dimensions of knowledge in creative and interconnected relationships with people, places and the natural environment (per SSHRC definition of Indigenous research).

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| **22.** | **Marginalized:** | Members of society that face exclusion due to societal and systemic barriers (adapted from Glossary: Canadian Centre for Diversity and Inclusion). |
| **23.** | **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 (adapted from Glossary, TCPS). |
| **24.** | **Multi-Jurisdictional Research:** | Research involving multiple institutions and/or multiple REBs. It is not intended to apply to ethics review mechanisms for research involving multiple REBs within the jurisdiction or under the auspices of a single institution (adapted from Glossary, TCPS). |
| **25.** | **Ongoing Research:** | Research that has received REB approval and has not yet been completed (adapted from Glossary, TCPS). |
| **26.** | **Participant:** | An individual whose data, biological materials, or responses to interventions, stimuli, or questions by an individual conducting research are relevant to answering the research question(s). Also referred to as a “human participant,” and in other policies/guidance as “subject” or “research subject” (adapted from Glossary, TCPS). |
| **27.** | **Principal Investigator (PI):** | The principal investigator is the lead researcher who provides overall intellectual leadership and direction of the research and related activities. The PI may may be designated as the applicant or co-applicant on a research funding application and may be responsible for the financial and administrative aspects of the project according to their defined role. The PI must be qualified to undertake the research independently, cannot be a student, has the necessary expertise to guide members of research team, and meets the eligibility criteria for their defined role. The PI |

takes responsibility for the responsible conduct (including ethical conduct) of the research, and for the actions of any member of the research team at a local site (adapted from NSERC CCI program and Glossary, TCPS).

Note: For student research, the qualified researcher (typically the faculty member) guiding the student(s) shall function as the PI for the purposes of this Policy.

**28.** **Research:** An undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation (adapted from Glossary, TCPS).

**29.** **Research Ethics Board (REB):** A body of researchers, community members, and others with specific expertise (e.g., in ethics, in relevant research disciplines) established by an institution to review the ethical acceptability of all research involving humans conducted within the institution's jurisdiction or under its auspices (adapted from Glossary, TCPS). It may also be referred to as an Human Research Ethics Board (HREB).

**30.** **Risk:** The possibility of the occurrence of harm. The level of foreseeable risk posed to participants by their involvement in research is assessed by considering the magnitude or seriousness of the harm and the probability that it will occur, whether to participants or to third parties (adapted from Glossary, TCPS).

**31.** **Scholarly Review:** Specific to this policy framework, scholarly review is the process by which objective and independent experts from relevant disciplines critically assess the quality of a research proposal by reviewing its scientific merit (i.e., design, methodology, validity, feasibility, and relevance) and often originality, to ensure it meets scholarly standards.

**32.** **Standard Operating Procedures:** Standard operating procedures (SOPs) are institutional process documents developed together by the REB and Office of Research Services to operationalize procedures for conducting research with humans (adapted from McGill University REB).

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| **33.** | **Terms of Reference:** | A formal document that outlines the a board or committee's purpose, mandate, and governance. It typically defines operational procedures, review processes, the composition, the members' roles, and accountability. |
| **34.** | **Unanticipated Issues:** | Issues that: occur during the conduct of research; may increase the level of risk to participants or have other ethical implications that may affect participants' welfare; and were not anticipated by the Principal Investigator in the research proposal submitted for research ethics review (adapted from Glossary and Article 6.15, TCPS). |
| **35.** | **Underserved:** | Groups who face systemic barriers that prevent them from accessing or receiving the same quality of services as people not facing those barriers. (adapted from Glossary: Canadian Center for Diversity and Inclusion). |
| **36.** | **Vulnerability (adjective form Vulnerable):** | A diminished ability to fully safeguard one's own interests in the context of a specific research project. This may be caused by limited decision-making capacity or limited access to social goods, such as rights, opportunities and power. Individuals or groups may experience vulnerability to different degrees and at different times, depending on their circumstances (adapted from Glossary, TCPS). |

# B. PROCEDURES

## 1. Roles and Responsibilities

The ethical conduct of research involving humans is a responsibility shared across the institution.

a. Institutional Responsibility

The University is ultimately accountable for the research carried out in its own jurisdiction or under its auspices (per Article 6.1, TCPS). For fulfilling this responsibility, the University through the Office of Associate Vice President, Research and Innovation (or their delegate) shall:

i. establish or appoint an REB (or REBs in case of multiple boards) to review the ethical acceptability of all research involving humans conducted within its jurisdiction or under its auspices (per Article 6.1, TCPS) in accordance with TCPS;

ii. ensure the REB is provided with necessary and sufficient ongoing financial and administrative resources to fulfill their duties (per Article 6.2, TCPS);

iii. grant the REB the mandate to review the ethical acceptability of research on behalf of the university, including approving, rejecting, proposing modifications to, or terminating any proposed or ongoing research involving humans. This mandate shall apply to research conducted under the auspices or within the jurisdiction of the university, using the considerations set forth in TCPS (per Article 6.3, TCPS);

iv. authorize its REB to accept reviews undertaken by an external REB of the ethical acceptability of research. The approvals are based on cross-institutional agreements involving several REBs as outlined in TCPS (per Articles 8.1 and 8.2, TCPS);

v. ensure that the membership of the REB is designed to ensure competent and independent research ethics review;

vi. ensure that a well-functioning REB is appropriately composed and structured, according to the TCPS (per Article 6.4, TCPS). To ensure the independence of REB decision making, institutional senior administrators shall not serve on the REB;

vii. ensure that the REB has provisions for consulting ad hoc advisors in the event that it lacks the specific expertise or knowledge to review the ethical acceptability of a research proposal competently (per Article 6.5, TCPS);

viii. establish the terms of REB members to allow for continuity of the research ethics review process (per Article 6.6, TCPS);

ix. appoint a Chair for the REB who provide overall leadership for the REB and to facilitate the REB review process, based on institutional policies and procedures and TCPS (per Article 6.8, TCPS);

x. establish quorum rules for REB that meet the minimum requirements of membership representation outlined in Article 6.4 of TCPS (per Article 6.9, TCPS);

xi. take responsibility for appointment, renewal and removal of members of the REB (per Article 6.2, TCPS);

xii. ensure that appropriate resources, training and facilities are allocated to the REB, as dictated by TCPS (per Article 6.7, TCPS);

xiii. recommend, develop, and implement educational opportunities and develop resources for individuals conducting research involving humans, in collaboration with the REB;

xiv. provide administrative support for the ethics review process, approvals and ongoing regulatory activities (per Article 6.2 TCPS);

xv. ensure that processes are in place so that research involving humans is preceded by a REB approval;

xvi. enter into any agreements with other institutions to conduct the ethics review and approval of research involving humans under the auspices of KPU (per Article 6.7, TCPS);

xvii. establish appropriate institutional security safeguards to protect research data held at the university and participant confidentiality, train researchers and REB members on privacy best practices (per Articles 5.4, 6.2 and 6.7, TCPS, and related ORS Guidelines);

xviii. investigate allegations of non-compliance and instigate Continuing Research Ethics Review monitoring where required (per Article 6.15, TCPS); recommend additional training resources to the researcher as needed;

xix. have an established mechanism and a procedure in place for promptly handling appeals from researchers when, after reconsideration, the REB has refused ethics approval of the research (per Article 6.19, TCPS);

xx. facilitate ethical partnership between researchers and communities and ensure relevant training resources are available for researchers (per Chapters 9 and 10, TCPS; and related Guidance Document);

xxi. ensure a process is in place for the review and approval of SOPs as per university policy and legal requirements;

xxii. develop and implement conflict of interest polices including procedures to identify, eliminate, minimize or otherwise manage conflicts of interest that may affect research and compromise participants' protection (per Article 7.1 TCPS) and disclose such conflicts to REB through established conflict of interest mechanisms (per Article 7.2 TCPS); and

xxiii. provide a framework for administrative reviews and administrative approvals (e.g. in accordance with policies, agreements, and laws) for research

b. Responsibilities of Principal Investigator

The principal investigator (PI) provides intellectual leadership to the project and the project team. The PI has the responsibility to ensure that all research is conducted responsibly by the project team.

Specifically, all PIs who plan to conduct research involving humans must:

i. comply with KPU policy frameworks relating to research;

ii. request the REB to determine whether any research involving humans that they, their research team, or the students under their direction are proposing to undertake is subject to REB review (per Articles 2.1-2.6, TCPS): the authority to determine whether or not that research is exempt from REB review or not rests solely with the REB (per REB Guidance Document for ethics exemptions);

iii. submit an ethics application with sufficient information for the REB to assess whether the proposed research complies with the TCPS and ensure that all required prior approvals are in place before commencement of activities requiring such prior approval. Specifically, REB review and approval of the ethical acceptability of research are required before recruitment, data collection involving participants, access to data, or collection of human biological materials: such requirements are also applicable to human genetic research or that involve use of human biological material (per Article 6.11 and Chapter 5 Section D, Chapter 12 TCPS; and related REB Guidance Document);

iv. conduct all REB approved research in accordance with the TCPS, relevant KPU policy frameworks, SOPs, guidance documents and other legal obligations (e.g. human rights) and commitments;

v. consider the international/legal requirement of jurisdiction outside of Canada (Chapter 1, Article 1.1 and Chapter 8, TCPS) for research involving global participants;

vi. establish and implement appropriate research data management plans according to disciplinary best practices, including procedures for the collection, use, storage, security, disclosure, and disposal of

data (per related REB Guidance Document and Chapter 3 Section E and Chapter 5 Article 5.3 and 5.7 TCPS);

vii. ensure full disclosure and informed consent from participants about how their data will be used, through informed consent templates and research data management plan templates. (per related REB Guidance Document and ORS Guidelines);

viii. promptly report to the REB any Unanticipated Issues in accordance with TCPS (per Articles 6.13 and 6.15, TCPS; and related REB Guidance Document) including any unanticipated issue that increases the level of risk to participants or has other ethical implications that should be reported without delay;

ix. ensure ongoing research approvals are in place, including applying for Continuing Research Ethics Review of research by submitting a progress report as per required timelines and securing renewal of the existing REB approval prior to expiry of such approval (per Article 6.4, TCPS);

x. immediately notify the REB of any proposed modifications (e.g. involving recruitment, design, data collection or storage) by submitting a request for amendment (per Article 6.14 and 6.16, TCPS) while recognizing that in some types of qualitative research, for example, emergent design (per Article 10.5, TCPS), the research design evolves over time, and so adjustments to the research are to be expected and need not be reported to the REB, unless they alter the level of risk or have other ethical implications for participants (per Article 6.16, TCPS);

xi. implement amendments only after the REB has reviewed and approved them.

xii. submit a completion report to the REB once the research has concluded, in a timely manner (per Article 6.14, TCPS);

xiii. guide all research team members in conducting research responsibly and ensure that the members engaged in research complete all required training (such as the TCPS Course on Research Ethics for research involving humans) prior to commencement of work on the project (per Article 6.14, TCPS);

xiv. be aware of relevant ethical duties that govern real, potential or perceived conflicts of interest related to the consent of participants,

especially cognizant of conflict of interest that may arise from their dual roles such as a researcher and a supervisor (per Article 3.2(e) and 7.4, TCPS and and related REB Guidance Document);

xv. demonstrate the steps they have taken to engage with their communities and other considerations based on principles of community-based research outlined in TCPS and university guidelines (per Chapters 9 and 10, TCPS; and related REB Guidance Document);

xvi. demonstrate due preparation in addition to a high degree of sensitivity, ethical awareness, and adherence to guidelines such as TCPS while working with vulnerable, marginalized, equity-denied, and underserved populations (related to Article 4.7, TCPS; and related REB Guidance Document);

xvii. be informed of guidance documents from KPU and the Panel on Research Ethics for recruiting participants, the consent process, and payments to participants where required (also related Guidance Document from REB);

xviii. respectfully partner with Indigenous peoples to develop and undertake Indigenous research in accordance with Chapter 9 of TCPS and the Pulling Together: A Guide for Researchers, Hiɬk̲ala: A guide for Indigenization of post-secondary institutions.

c. Responsibilities of Principal Investigators as Supervisors of Student Research

i. All student research must be supervised by a qualified researcher who serves as PI and accepts responsibility for overseeing the ethical conduct of the student's research (further to RCR Framework Interpretations: Appropriate supervision and training in the conduct of research related to Article 2.7 of RCR Framework, per Article 6.14, TCPS and related REB Guidance Document);

ii. Student research supervisors should act as a resource for the student when preparing an ethics application and must review the application prior to submission. They must:

1) ensure that their students have up-to-date training and competence necessary to conduct the proposed research;

2) guide students with preparing application for REB review;

3) submit or otherwise endorse the application for REB review;

iii. establish and implement appropriate DMPs; (per related REB Guidance Document and Chapter 3 Section E and Chapter 5 Article 5.3 and 5.7 TCPS);

iv. ensure that all requirements of the ethics approval are met.

d. Responsibilities of the REB

The REB ensures that KPU adheres to the TCPS as well as any applicable institutional (per REB Terms of Reference), national, and provincial requirements. To fulfill this responsibility, the REB shall:

i. review on behalf of KPU all proposed or ongoing research involving humans conducted under the auspices of KPU in a way that is consistent with this Policy and all applicable ethics guidelines (per Article 6.4 TCPS);

ii. approve, reject, propose modifications to, terminate, or suspend any proposed or Ongoing Research involving humans (per Article 6.3 TCPS) based on the ethical acceptability of the research;

iii. conduct Continuing Research Ethics Reviews on an annual basis at a minimum

iv. report the outcome of an ethical review to PI in a clear and timely manner (per Article 6.14 TCPS);

v. as part of the research ethics review, the REB shall review the ethical implications of the methods and design of the research and if required, conduct a scholarly review. Research that poses more than minimal risk requires scholarly review. (per related REB Guidance Document; and per Article 2.7 TCPS);

vi. require the protection of participants' privacy, assessing the risk of re-identification in human genetic research, and evaluating risks associated with the use of human biological materials through a proportionate and context-sensitive ethics review process (per Article 6.11, Chapter 5 and 12 TCPS, related Guidelines and SOPs);

vii. prepare and maintain minutes of all REB meetings and include all attendance, decisions, and dissents, and the reasons for them. REB decisions should be supported by clear references (e.g., date of decision), timelines, reasoning and limitation (per Article 6.17 TCPS);

viii. contribute to development and implementation of guidance documents, policies, and procedures for ethical research involving humans (per Article 6.12, TCPS; all online under guidelines and resources: REB SharePoint)

ix. declare actual, perceived, and potential conflicts of interest associated with all reviews and recuse oneself when a conflict of interest exists or is declared to exist by the Chair (per Article 7.3 TCPS);

x. collaborate with other REBs on the review of multi-jurisdictional research (per Article 8.1, TCPS and BC Research Ethics Review Reciprocity Agreement);

xi. take appropriate steps to ensure researchers are responsive to ethically relevant aspects of research context, for research conducted across multiple global sites (per Article 8.3 TCPS);

xii. establish, when appropriate, its own internal guidelines that do not conflict with those approved by University governance or the TCPS;

xiii. meet regularly to further its mandate (per Article 6.10, TCPS);

xiv. ensure the quorum is met during meetings as required by TCPS (per Articles 6.4 and 6.9, TCPS, and REB Terms of Reference);

xv. prepare and submit an annual report on its activities in a format and timeline provided by the Office of Associate Vice President, Research and Innovation, to that Office. Following approval from the Associate Vice President, Research and Innovation, submit it to the relevant executive and governance bodies at the University for information, as well as publish online as a public document.

xvi. engage in training periodically to ensure the REB is up-to-date on current legal and regulatory requirements, ethical standards and policies (per Article 6.7, TCPS);

xvii. promote training that encourages ethical conduct of research at KPU;

xviii. regularly review and update (preferably every year, but at least every three years) its guidance documents to meet current ethical standards and policies;

xix. collaborate with the Office of Research Services to develop and update SOPs as required;

xx. require that all data collection, management, usage and storage procedures adhere to ethical standards (including Indigenous data sovereignty) and legal requirements, including obtaining informed consent from participants (and communities, where applicable) and implementing appropriate measures to safeguard confidentiality and privacy throughout the research process (Chapter 5, Articles 5.4, 6.2 and 6.7 TCPS; Pulling Together: A Guide for Researchers, Hiɬk̲ala: A Guide for Indigenization of Post-secondary Institutions; related REB Guidance Documents and ORS Guidelines);

xxi. review research that involves communities, based on the community-based research protocols and guidelines outlined in the TCPS (Chapter 9, TCPS and related REB Guidance Documents);

xxii. fulfil its duty of care by advising PIs, and/or university research administration about any concerns (ethical or otherwise) identified during the review process that pose harm;

xxiii. ensures timely response mechanisms are in place, such as for unexpected harms (per Article 6.15, TCPS) or adverse incidents (per Article 11.9, TCPS). Establish procedures for reviewing such events and determine how to respond and implement these responses as needed (also see related REB Guidance Document);

xxiv. foster training for researchers to increase understanding of ethical conduct of research involving humans; and

xxv. review Indigenous research in accordance with Chapter 9 of TCPS, and the Pulling Together: A Guide for Researchers, Hiɬk̲ala: A Guide for Indigenization of Post-secondary Institutions.

**2. Membership of the REB**

a. The REB shall consist of at least five members as required by TCPS (per Article 6.4 TCPS). KPU shall also consider the nomination of substitute REB members so that REBs can continue to function when regular members are unable to attend due to illness or other unforeseen eventualities. The appointment of substitute members should not, however, alter the REB membership composition. Substitute members should have the appropriate knowledge, expertise, and training to contribute to the research ethics review process;

b. In addition to regular members and substitute members, the REB may consult with non-members such as Ad Hoc Advisors where it lacks the specific expertise

or knowledge to review the ethical acceptability of a research proposal competently. Ad Hoc Advisors shall not be counted toward a quorum, and they are not allowed to vote on REB decisions (per Article 6.5, TCPS);

c. Recruitment of REB members will follow an open, transparent, and inclusive competition, with a selection process that is fair, impartial, and free from any bias or discrimination, organized by the Office of Associate Vice President, Research and Innovation or their designate;

d. To ensure the independence of REB decision-making and to avoid perceived conflicts of interest, institutional senior administrators shall not serve on the REB (per Article 6.4, TCPS);

e. All members of the REB are appointed by the Associate Vice President, Research and Innovation for a continuous (without any breaks) term of up to three years, with the possibility of renewal for a further term up to three years (per Article 6.6, TCPS and REB Terms of Reference). The terms shall be arranged and membership rotated to balance the need to maintain continuity with the need to ensure diversity of opinion, and the opportunity to spread knowledge and experience gained from REB membership throughout the institution and community;

f. The Chair of the REB must be a qualified member who is responsible for ensuring that the REB review process conforms to the requirements of TCPS. The Chair provides overall leadership for the REB and facilitates the REB review process, based on institutional policy frameworks (especially those related to research) and TCPS. The Chair monitors the REB's decisions for consistency and ensure that these decisions are recorded accurately and communicated clearly to researchers in writing as soon as possible (per Article 6.8, TCPS);

g. The Chair will be appointed by the Associate Vice President, Research and Innovation following an open, transparent, and inclusive competition (open to all current REB members in good standing) based on the recommendation by a nomination committee struck by Associate Vice President, Research and Innovation (Terms of Reference for REB Chair and Vice Chair Nomination Committee; REB Terms of Reference);

h. The Chair will serve a continuing term of up to three years, renewable once on the recommendation of the nomination committee, for a maximum of two terms at a time;

i. The Vice-Chair must be a qualified member of REB whose role is to fulfill the role of the Chair when the Chair is unavailable, or there is a conflict of interest declared by the Chair (REB Terms of Reference);

j. The Vice-Chair shall be appointed by the Associate Vice President, Research and Innovation following an open, transparent, and inclusive competition (open to all current REB members in good standing) based on the recommendation of the nomination committee.

k. The Vice-Chair shall serve, a continuing term of up to three years, renewable once on the recommendation of the nomination committee (REB Terms of Reference);

l. The composition of committees to select or recommend members, chair, and vice chair of the REB shall reflect the diversity, expertise, and judgement needed to critically assess the competence of applicants applying for these various roles. The committees shall draw their membership from current or former members, chairs, or vice chairs of the REB, in addition to research services personnel supporting the REB. The selection or nomination processes shall be fair, impartial, and free from any bias or discrimination, and rely on open, transparent, and inclusive competitions; and

m. An REB member may resign or be removed in accordance with the REB Terms of Reference.

**3. Procedures for Review of New and Ongoing Research**

a. The REB will use 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 (per Articles 2.7 and 2.9, TCPS; REB Terms of Reference).

    i. the lower the level of foreseeable risk to participants or their communities, the lower the level of scrutiny (delegated review); and

    ii. the higher the level of risk, the higher the level of scrutiny (Full Research Ethics Review);

b. A proportionate 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 (Chapter 1 section C, Article 2.9 and 6.12 TCPS);

c. Full REB Reviews are conducted at a REB meeting while minimal risk research can usually be reviewed by delegated REB review;

d. Delegated REB Review is used for research assigned as minimal risk. Delegated reviewers are selected from among the REB membership, with the exception of the ethics review of minimal risk student course-based research activities, which can be reviewed by the faculty or instructor delegated from the student's department, faculty, or an equivalent level (per Article 6.12, TCPS);

e. Delegated reviewers who are not members of the REB must have experience, expertise and knowledge comparable to what is expected of a REB member;

f. Ethics Approvals are issued for a period of no more than one year. Renewal is required for multi-year study.

**4. Scholarly Review Process**

a. Research in the humanities and social sciences posing more than minimal risk requires an independent scholarly review, which may be internal or external depending on the study's complexity (adapted from Article 2.7 TCPS; and related REB Guidance Document*)*;

b. The appropriate type of review depends on the nature of the study and individuals are encouraged to consult with the Office of Research Services for assistance. For student thesis projects, the supervisory committee's approval is deemed to constitute sufficient scholarly review;

c. PI must detail any scholarly reviews in the university's electronic research administration system, including whether the review is ongoing or completed, and upload corresponding reports.

**5. Unanticipated Issue - Incident Reporting**

In conducting their approved research, should unanticipated issues arise that may increase the level of risk or have other ethical implications, researchers shall report them to REBs in a timely manner (per Articles 6.14 to 6.16, 11.6 and 11.8, TCPS and related REB Guidance Document);

a. The PI should report 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;

b. PIs must complete and submit an Incident Reporting Form to the REB for the unanticipated issue as early as reasonably possible as per this procedure and guidance documents;

c. Upon receiving an Incident Reporting Form, the REB will review and may recommend changes to mitigate risks, including modifying recruitment methods, informing participants of new risks, or pausing research activities until issues are resolved and risks are adequately addressed.

**6. Course-Based Student Research (CBSR)**

a. A CBSR application is required when an instructor seeks to supervise student research involving humans in the context of a course (per related REB Guidance Document). The research activities are supervised by the instructor, who, upon approval, is delegated by the REB to assess and monitor the ethics of student research according to the principles, guidelines, and requirements of the TCPS. Even when students collect data from peers in the same course, this is still considered CBSR and requires REB approval;

b. The TCPS (per Article 6.12, TCPS) allow institutions to delegate ethics review of minimal risk course-based research activities with a pedagogical purpose to non-REB members at the institution's department, faculty or equivalent level. Thus, the objectives of CBSR research must be educational;

c. If a student research project begins with approval of an REB Protocol for CBSR and later expands outside the scope of approved activities, a regular application for ethical review must be approved by the REB prior to recruitment of participants and/or collection of research data;

d. Instructors cannot use data collected under a CBSR approval for their own research without documented consent for such use. They are responsible for storing and disposing of students' data appropriately;

e. Instructors are eligible to complete a Course-based Research Ethics Application for students' activities and assignments under the following conditions:

    i. Within the course presentation, instructors set parameters and instructions for students as to the research skills and conditions under which students will undertake activities;

    ii. Instructors supervise and teach students about conducting one or more research activities (e.g., students practice recruiting

participants, collecting data, interpreting data, compiling the data in various formats, and reporting on findings); and

iii. All students complete and submit proof of completion of the required research ethics training (such as the TCPS CORE certificate) to the instructor before beginning any research activities;

f. The course instructor is responsible for the ethical conduct of all student research activities conducted under the auspices of the course;

g. CBSR cannot be used for capstone projects, undergraduate theses, or research linked to an instructor's or faculty member's research program. In such cases, students must be added to an existing REB approval as research assistants through an amendment process. (per Articles 2.1 and 6.12 TCPS, and related REB Guidance Document).

**7. Reconsideration of REB decisions**

a. PI has the right to request, and the REB has the obligation to establish timelines to promptly conduct reconsiderations and issue the decision (per Article 6.18, TCPS);

b. Initial reconsideration may consist of informal discussions involving the PI and the REB. If the matter is resolved through this process, the resolution will be documented in the online application system and will also be reflected in the application materials as appropriate;

c. If informal discussions do not lead to a resolution, the PI may request a formal reconsideration in writing to the REB Chair, outlining the concerns they have with the initial REB review;

d. The PI has the right to be heard in a meeting with the REB to discuss the issues identified; and

e. When requesting reconsideration, the onus is on the PI to justify the grounds on which the reconsideration is requested and to indicate any alleged breaches to the established research ethics review process, or any elements of the REB decision not supported by the TCPS (per Article 6.13, TCPS) or this Policy framework;

## 8. Appeal process

a. If the PI is not satisfied with the outcome of the reconsideration, the PI may file a written request for an Appeal to REB decision with the Associate Vice President, Research and Innovation within 30 calendar days of the reconsideration (per Article 6.19, TCPS and related ORS Guideline), following the process outlined below:

   i. KPU shall have an agreement with another Canadian institution, whose REB shall function as an Appeal Board for the purposes outlined in this Policy;

   ii. A researcher wishing to formally Appeal a decision of the KPU REB to reject a human research ethics application or an amendment request or to rescind approval of ongoing research (the Appellant) must engage in the reconsideration process described above; Within 30 calendar days of receipt of notification of the REB's decision following its reconsideration;

   iii. The Appellant shall provide the Office of Associate Vice President, Research and Innovation with the following:

      1) the application, as submitted to the REB; and

      2) a statement of the basis of the appeal (procedural, substantive, or both) and the rationale for the appeal;

   iv. The REB Chair or designate will provide to the Office of Associate Vice President, Research, Innovation, the REB materials specified in the appeals agreement as follows;

      1) a written statement of the final decision of the REB and a written rationale for the decision

      2) copies of minutes of the meeting(s) that the REB discussed and made the decision.

      3) Copies of the materials and resources that the REB consulted in making the decision

   v. The Associate Vice President, Research and Innovation or designate shall forward all above materials to the Appeal Board;

   vi. The Appeal Board shall have the authority to review negative decisions made by an REB. In so doing, it may approve, reject or

request modifications to the research proposal (per Article 6.20 TCPS);

vii. Appeal Board decisions on behalf of the university shall be final and should be communicated in writing (in print or by electronic means) to researchers and to the REB whose decision was appealed. Recourse to judicial review may be available to the researcher (per Article 6.20, TCPS)

viii. The PI acknowledges receipt of the decision in writing to Office of Research Services within five working days of receiving the decision and provides assurance to comply with the decision (per Article 6.20, TCPS).

**9. Use of Generative Artificial Intelligence Technologies**

All members of the University community are to consult and comply with the upcoming Guideline on Enabling Responsible Use of Generative AI for Research which provides guidance on the appropriate use of generative artificial intelligence technologies across the life cycle of research activities. Of particular importance to researchers are considerations of full disclosure and informed consent from participants in use of such technologies, and full disclosure on applications and amendments submitted to the Research Ethics Board when proposing the use of such technologies as part of research projects involving humans.

## C. RELATED POLICY

RS1 Research Involving Humans