



RESEARCH ETHICS BOARD

GUIDE TO THE APPLICATION FORM FOR ETHICS REVIEW

The following guide explains how to use the Kwantlen University College research ethics policy in filling out an application for ethics review. The numbers correspond to those on the application form. The application form is reproduced here with guideline items below numbered sections of the application. The items marked G are guidelines.

Application for review of a research proposal by the Research Ethics Board

Participation in research does not simply involve research experience, procedure, and protocol but also a human relationship where there is a commitment to communication, trust, mutual respect and cooperation in meeting the interests of all involved. The research ethics approval process is also such a human relationship.

Unless expressly exempted, all research under the auspices of Kwantlen University College and all research on our campuses that involves living human subjects requires prior review and approval by the REB. This includes research in which there are researchers and/or participants who are not Kwantlen employees or students.

In signing your application for review you accept that you have read, understood, and abide by the Kwantlen University College policy, and abide by the attached Kwantlen University College Policy.

Researchers have a responsibility to ensure their research is conducted in a manner consistent with federal and provincial laws and regulations. They also have a responsibility to adhere to the code of ethics for their particular profession or field.

This form will provide a brief, but clear and complete synopsis of your proposal/project.

Answer every question. If a question does not apply to your protocol, indicate "not applicable" and explain why it is not applicable. The numbering of the instructions corresponds to the numbering on the form. Note: If this research received ethical approval from another institution, please submit a copy of the application and the certificate of approval.

The procedures of the REB may sometimes be difficult to follow in some kinds of research. Researchers should discuss problems with the REB so that reasonable variation may be permitted.

1. Full title of research. Administration use only application number

G: This should be the same title as on the cover page but may include more detail in subtitles.

2. Describe the purpose of the research.

G: In a summary paragraph, please describe the aims, purposes, and/or objectives of the research.

Indicate whether the research is sponsored (funded) or not. Normally, the REB will not undertake the review of a project for which funding is sought until the sponsor approves funding. Please note allowance has to be made for the review time and its impact on the projected start date for the research. If the research is being undertaken at another site, approval and/or permission must be obtained from these sites as well. This may involve another ethics board or a less formally structured process.

3. Describe the research question or hypothesis to be tested if known.

G: If the research is exploratory, please describe the general area within which the research is aimed at framing hypotheses.

4. Describe the methodology of the research study/project.

G: Please highlight the methods in a summary paragraph. Include any questionnaires or protocols where applicable.

5. Describe the method(s) of recruiting participants.

G: Please include advertisements, notices, posters, or other instruments of recruitment. Telephone or direct approaches should be described fully and clearly "Recruitment of Research Participants".

Recruitment via Unsolicited Telephone or Internet Contact

The use of unsolicited telephone or Internet contact to recruit research participants can be problematic. If you intend to use this method, please provide your rationale. Investigators who plan to use these types of recruitment will have to prove to the REB that no other recruitment technique is feasible. They are encouraged to register their research project with the police, in case concerned citizens report the research to the police.

Exceptional diligence is required by faculty managing student researchers using this kind of recruitment because of its inherent difficulties.

Third Party Recruitment

When participants' names must be obtained from a third party who is obligated to maintain the confidentiality of their relationship (e.g. the physician/patient relationship), the third party must ask the participants for permission to release their names to the researcher.

6. Describe the participant groups in this study.

G: Selection criteria should be clearly identified (i.e., age, gender, race, education, religion and specific status, learning disabled, etc.). Describe any exclusionary procedures for ruling out some who respond to recruitment. Give your rationale for your sample size if you are doing work that involves statistical sampling.

7. Will the study involve any potential risks to the participants? If so, please describe the risks. See the guidelines for examples.

G: What is the probability of harm: low, medium or high? What are all the foreseeable harms: physical, emotional, psychological, social, political, financial, legal or others?

8. **Describe your informed consent procedures where applicable. Where it is not applicable, explain why it is not, e.g. where one is studying the public activities of politicians who have agreed to publicity, consent is already given. Submit the informed consent form and your participant information form with this application if these are used. See the guidelines for required elements. See also 9 below. If you do not plan to use a written consent form, then provide a rationale and indicate your alternative procedures where consent is relevant. (Be sure to consider all of the elements of the Requirement for Free and Informed Consent in the guidelines.)**

G. Required Elements for Informed Consent.

Requirement for Free and Informed Consent

- a) Simple, direct language easily understood by all participants must be used on forms or in verbally obtained consent.
- b) Research governed by this Policy may begin only if prospective subjects, or authorized third parties have been given the opportunity to give free and informed consent about participation, and their free and informed consent has been given and is maintained throughout their participation in the research.
- c) Evidence of free and informed consent by the subject or authorized third party should ordinarily be obtained in writing. Where written consent is culturally inappropriate or 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.
- d) It is required that all researchers provide contact information in a take away format to the research participants. The information is to include the researcher's name and phone number as well as the name and phone number of the Office of Research and Scholarship should they have questions the researcher cannot answer.
- e) The REB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set for the above, or waive the requirement to obtain informed consent, provided that the REB finds and documents that:
 - i. the research involves no more than minimal risk to the subjects;
 - ii. the waiver or alteration is unlikely to adversely affect the rights and welfare of the subjects;
 - iii. the research could not practicably be carried out without the waiver alteration;
 - iv. whenever possible and appropriate, the subjects will be provided with additional pertinent information after participation; and
 - v. the waived or altered consent does not involve a therapeutic intervention;
 - vi. biographies, artistic criticism, or public policy research do not require consent of the subject.
- f) In studies including randomization and blinding, neither the research subjects nor those responsible for their care know which treatment the subjects are receiving before the project commences. Such research is not regarded as a waiver or alteration of the requirements for consent if subjects are informed of the probability of being assigned to one arm of the study or another.
- g) Researchers shall provide, to prospective subjects or authorized third parties, full and frank disclosure of all information relevant to free and informed consent. Throughout the free and informed consent process, the researcher must ensure that prospective subjects are given adequate opportunities to discuss and contemplate their participation. At the commencement the prospective subjects shall be provided with
 - i) information that the individual is being invited to participate;
 - ii) a comprehensive statement of the research purpose, the identity of the researcher, the expected duration and nature of participation, and a description of research procedures;
 - iii) a comprehensive description of reasonably foreseeable harms and benefits that might arise from research participation;

- iv) an assurance that prospective subjects are free not to participate, have the right to withdraw at any time without prejudice to pre-existing entitlements, and will be given continuing and meaningful opportunities for deciding whether or not to continue to participate; and
- v) the possibility of commercialization of research findings, and the presence of any apparent or actual or potential conflict of interest on the part of researchers, their institutions or sponsors.
- vi) Participants' consent to audio taping, videotaping or still images must be fully informed with respect to editing or any alteration of data and to known future uses to which data will be put. Additional consent is required if new uses for the data are made in future.
- vii) When participants withdraw during a study, normally data collected up to that point may be used. Participants, however, could ask for particular harmful data to be removed, e.g. a phrase spoken on videotape could be beeped out. This would normally be done in negotiation between the researcher and the participant either of whom may involve the REB.
- viii) When a researcher contemplates new uses of raw data above and beyond those for which consent was given which could have harmful effects on participants or the groups to which they belong, additional consent must be sought from participants before the data is used again. The Research Ethics Board must review the new consent. If a completely new study results, then this must be approved by the Research Ethics Board.
- h) Where informed consent is verbal rather than written, the REB should be provided in writing with the information that will be conveyed verbally to participants. This information should comply with the REB guidelines on the elements of informed consent, including any assurances of confidentiality that are mentioned in the application to the REB.
- i) **Minors and Consent to Minimal-risk Research**
 - i) A minor is anyone who is under the age of 19.
 - ii) A minor who meets the legal test for a "mature minor" has the capacity to consent to participate in research without involving parents or guardians.
 - iii) A minor is considered in law to be "mature" when the minor understands
 - a. the nature of the study; and
 - b. the consequences of participating in the study, including any risks or foreseeable benefits.
 - iv) The adult with ultimate responsibility for the research study is also responsible for determining that a participant meets the test for a mature minor. This task may be delegated to someone knowledgeable about the study who has the ability to assess a minor's understanding, but the person doing the assessment should not be a minor.
 - v) The decision that a potential research participant is a mature minor should be documented, and a note made of the reasons for that decision. It is also advisable to record questions asked by the minor that demonstrate his or her understanding of the research.
 - vi) If there is doubt about whether or not a potential research participant is a mature minor, he or she should not be enrolled in the study.

9. Where deception is used, please include your rationale and debriefing procedures.

G: See 8 above. Where applicable, please tell us how you provide participants with referrals for counseling or other support and debriefing following the study. (Where these procedures are not applicable, explain why not.)

10. What provisions are made for informing participants, for follow-up with participants?

G. Debriefing

At the conclusion of the study, participants should be debriefed. Debriefing serves two purposes. First, it is used to remove any negative states that may have been induced by the research (e.g. in mood manipulation studies). Second, it is used to disclose information about the research so that participants may fully benefit from the research. Debriefing may include referral to further assistance, e.g. counseling support.

Full Disclosure of Information

To maximally benefit from the research, participants should learn something either about themselves or about the topic of the research. Consequently, using simple language, researchers should fully disclose to participants the purpose of the research and describe how the data from the study will be used. As well, when possible, researchers should describe the research context, hypothesis tested, experimental procedures, and any provisional results (including the participants' individual results if this information is available and the participant requests it). Researchers should endeavour to answer participants' questions fully after the experiment, and should provide participants with information about how they can get more information afterwards. Typically, a contact address or telephone number is provided.

Use of Deception During an Experiment

In some situations, it may be necessary to use deception because there is no other valid way to conduct the proposed research (e.g., research on prejudice, altruism, aggression, incidental learning, unconscious influences on behaviour). Nonetheless, researchers should strive to minimize the amount of deception in their research. The use of deception is subject to the restrictions listed below:

- a) Research participants should never be deceived about the tasks they will be required to perform or factors that would affect their decision to participate in the experiment (such as potential harms or benefits and time commitment). In particular, whenever there is a risk of harm, deception should not be used.
- b) Deception is not permitted when it is not possible to inform participants about how they were deceived or why deception was necessary at the conclusion of the study.
- c) In the submission for ethical approval, the principal investigator must provide evidence and/or strong arguments that show a significant scientific advance could result from the experiment and that a procedure that does not involve deception would not work as well.
- d) When deception is used in a study, research participants should be fully informed of it as quickly as possible at the conclusion of the experiment during the debriefing. All deception should be removed and full disclosure should be made. In particular, participants should be told of the real purpose of the research and the actual procedures involved. They should be told why deception had to be used in the experiment, and why there was no alternative to its use.

11. How do you plan to handle the requirement of confidentiality and/or anonymity where applicable?

G: Anonymity entails the collection of data not linked to any particular participant, thus, non-identifying data. Confidentiality entails data and consent forms and any other material with personal information about participants that is linked to a participant either directly identifying or by a particular code. In such cases, you need to ensure that any potentially identifying data is handled appropriately. Please provide details as to the storage and ultimate disposal of records/data and consent forms—(l) what precautions will be taken to ensure that data is not

traceable to given subjects/participants; (ii) where this is not possible, who will have access to the data; (iii) where and how the data will be stored; and, (iv) for how long the data will be stored.

Required Elements for Confidentiality and/or Anonymity

Anonymity, Confidentiality and Privacy

The researcher should guard the participant's privacy by ensuring that individual results are confidential. This entails ensuring that each participant's data cannot be linked to his or her name, and that information about the identity of specific participants is not communicated in any way without the participants' specific consent. Special guarantees may be required for sensitive information (personality and intelligence test scores, academic grades, information about sensitive issues such as sexuality, mental and physical illness, physical and sexual abuse, substance abuse, death, illegal activities and all issues involving children as research participants). In general, it is best to assign each participant a subject code, and thus lose identity information about the participant as quickly as possible. In situations where it is learned that an individual has stated intent to do damage to her/himself, the researcher is required to take all reasonable steps to prevent this damage from occurring including informing others where that is effective.

The decision to include confidential information in the application for ethical review should be based on protecting the best interests of the participants. Please do not include information that could put individuals or organizations at risk unless this information is crucial to the ethical review of the study you propose. Even information about locations of organizations or activities can be sensitive

12. Describe any potential conflict of interest of anyone involved in the research.

G: See 8 above.

Conflict of Interest

Researchers employed by, responsible to, or working for another organization with an interest in the research, must inform the REB and research participants.

Researchers should avoid being the principal investigator where their responsibility to another organization may compromise objectivity.

Research activities by students should not go beyond what is required by the learning process. In particular, students must not be used for the financial benefit of Kwantlen University College or its employees.

13. Describe any provisions for compensation of participants if applicable.

This form must be resubmitted after approval if there are major changes to your study. See part C of the Kwantlen University College policy on post approval monitoring. Major changes include changes in protocol, consent, risks, participant groups, recruitment, compensation, deception, confidentiality, anonymity, researchers involved, or other ethically sensitive matters. Please highlight changes on the resubmitted form.

14. Surveys, consent forms, letters of introduction, recruiting materials, posters, advertisements and anything related to a research project without a completed review and approval of the Research Ethics Board should be withheld by the researcher until the final approval of that project by the board.

15 Automatic extensions of research studies for 6 months are available if nothing else at all has changed in the study but the end date. You need only inform the Research Ethics Board of the new end date.

16 Please avoid attachments in your communications with the REB by email. Copy whatever you want to send, including applications, into the email message.

17 Guidelines for Archival Studies

Researchers must try to avoid harm to all whose information is recorded in the archives. The researcher should not gain access to archives if that would involve the researcher in a conflict of interests. The researcher will normally not use archives of information that was gained by force or fraud. An exceptional justification would have to be given in such cases, e.g. an appeal to great benefits to be gained by the providers of the information.

Specific steps to take

In the application the researcher should

- a) reveal the source of all records used**
- b) explain the nature of records**
- c) say how these records will be used for the proposed research, and**
- d) identify potential risks to people mentioned in the archives and explain the steps to be taken to minimize these risks**

There are some further steps that may or may not be necessary. For each of the following steps, researchers should say how they will take the step, or say why they do not need to, or justify the study if this step is desirable but not feasible.

- e) indicate whether informed consent was obtained from those who supplied information and say whether they agreed to have information used in future studies**
- f) say what steps will be taken to obtain informed consent if there was none, or if consent will not be sought justify this**
- g) identify the steps to be taken to ensure anonymity and confidentiality**
- h) say how misappropriation will be avoided (e.g. through giving references to those who want them)**
- i) include a copy of written permission to use the archival data from the institution safeguarding the archival data.**

Date: _____

Signature: _____