RESEARCH ETHICS BOARD

GUIDELINES FOR COMPLETION OF AN APPLICATION FOR ETHICAL REVIEW

OF RESEARCH INVOLVING HUMAN SUBJECTS AND THEIR PARTICIPATION IN QUESTIONNAIRES, INTERVIEWS, OBSERVATIONS, TESTING, VIDEO & AUDIO TAPES, ETC.

INTRODUCTION

The guidelines, which include some of the OC Research Ethics Board's (REB) standard operating procedures and policies, are intended to ensure that the applicant has the necessary information to be able to complete correctly the Application for Ethical Review. These guidelines are numbered sequentially and correspond to the numbered box on the form. The OC REB procedures/policies correspond to, and comply with, the **Tri-Council Policy Statement** (TCPS) on 'Ethical Conduct for Research Involving Humans'. This document has its origin in the ethical principles that were developed in the Declaration of Helsinki (see Appendix 1 for the Guiding Ethical Principles from the TCPS).

The Principal Investigator is responsible for understanding and adhering to the TCPS and other relevant guidelines. These guidance notes are not to be a substitute. Please refer to the original documents for complete information - see website: http://www.ncehr-cnerh.org/english/code_2/

If you have any questions regarding the completion of any REB form, please address them to the REB Secretary at reb@okanagan.bc.ca or (250) 762-5445 Local 4561.

archival materials or third-

The turnaround time is approximately three weeks from the submission deadline, unless it is determined that the application requires additional information or changes.

CLASS PROJECTS

Class projects for research methods and other courses that require students to undertake research that involves human subjects in questionnaires, interviews, testing, observations, video and audiotape, and so forth must be reviewed and approved by the REB before the research begins. The instructor of the course should submit an Application for Ethical Review (Form 1). See Appendix 2 at the end of this document for further information.

REMOTE (TELEPHONE/INTERNET) CONTACT

Initial contact with subjects by telephone or internet is discouraged by OC REB. However, for surveys where sample selection is not on the basis of information held in confidence by a third

Appeal
When the investigators and the REB cannot reach agreement on a decision, the researcher can request the UBC Research Ethics Board to review the OC REB decision. TCPS Article 1.11 (a) on Appeals states: "In cases when researchers and REBs cannot reach agreement through discussion and reconsideration, an institution should permit review of a REB decision by an appeal board, provided that the board is within the same institution and its membership and procedures meet the requirements of this Policy." Requests for appeal should be directed to the Office of the Vice President of Education.

INTERIM APPROVALS

1. Written proof of agency consent is required for projects carried out at other organizations. When agency approval cannot be obtained without prior approval by the OC REB, a letter of conditional approval will be issued for submission to the agency if all other aspects of the proposal are satisfactory. Applications should be submitted concurrently to the OC REB and the agency.

2. Projects which require ethical review in order to obtain research grant funds with which to develop a questionnaire, survey or interview may receive conditional approval with the understanding that any part of the project dealing with human subjects cannot commence until the Board has formally approved a final proposal. Provide as much detail as possible on the preliminary Application for Ethical Review and state clearly in a cover letter that conditional approval is being sought.

APPROVAL PERIOD

Under Tri-Council policy, Ethics approval can only be given for one year at a time. If the study continues beyond one year, you will need to submit an Annual Research Status Report (Form 6) and, upon receipt and satisfactory review of this report, an Approval Certificate will be issued for a further one-year period. A project can only be approved through this mechanism for a maximum period of four years, after which a new ethics application must be submitted.

FACULTY/STAFF ENGAGED IN OUTSIDE PROFESSIONAL ACTIVITIES OR GRADUATE PROGRAMS AT OTHER UNIVERSITIES

Certain classes of research involving human subjects are excluded from the requirement for ethics review by the OC REB, including research that is being conducted by an OC faculty or staff member as 'Outside Professional Activity'.

Any outside professional activity that involves research should not assert any connection or affiliation with OC, should not be collec16(h Tm [(RO)2.7(G)2.MCID 20 a03.12 5.4 26.4 re Td ( )Tj

INSTRUCTIONS AND INFORMATION ON HOW TO COMPLETE THE APPLICATION FOR ETHICAL R

Research grants or contracts, administered by OC, will not be established until the project has been reviewed and approved by the REB. This information will be used to cross reference the Application for Ethical Review with a research grant or contract that may be flagged as pending ethical review. Please note that there must be an exact sponsor and title match between the grant and the Application for Ethical Review. For this reason, you may include multiple grants (sponsors) and titles in one Application for Ethical Review. Once received, the Certificate of Approval should be kept current by submission of an Annual Research Status/Renewal Request (Form 6) for the duration of the grant or contract.

Projects that require ethical review to obtain research grant funds with which to develop a questionnaire, survey or interview may receive conditional approval with the understanding that any part of the project dealing with human subjects cannot commence until the REB has formally approved a final proposal. Provide as much detail as possible on the preliminary Application for Ethical Review and indicate in a covering letter that conditional approval is being sought.

For research with more than minimal risk, the REB will need to satisfy itself about both the merit and the scientific validity of the study. It is helpful to the REB to have evidence of peer/scholarly review. The REB recognizes that there is a range of options for obtaining peer review, dependent on the nature and funding status of the study. For graduate student research, approval by the supervisory committee will be deemed sufficient. A copy of any peer review report from an external funding agency, if available, should be submitted with the Application. This copy need not exceed two or three pages in length. Any review process within a for-profit agency is not considered to be independent, and so is not sufficient.

Refer to TCPS Article 1.5, which states that Research Ethics Boards "may request the researcher to provide them with the full documentation of those [peer] reviews." Note that external peer review is not mandatory. Under some circumstances, depending on the level of risk, the REB may choose to defer a decision until peer review reports are available.

10. Title of Project

The title of the project should be as brief as possible to describe the area/focus of the project for which ethical approval is sought. The title given in this box should correspond with the title on the consent form.

If the study is supported by research grant or contract funding that is being administered by OC, the title in box 10 should also correspond to the title on the grant or contract. If the research project is supported by multiple grants with different titles, the ethics application should include the additional titles and the name of the corresponding granting agency.

11. Project Time Period

Provide the start date and end dates for the collection of all data. Researchers should be aware that the Board meets once a month and so the proposal should be submitted well in advance of any proposed start date (e.g., 2 months) in case of a need for extensive revision and/or re-application. **No research may be started** prior to receiving formal ethical approval. Retroactive approval is never permissible. The end date is understood to be approximate.

12. Title/Position of researchers involved in the project

Please indicate the positions of all researchers involved in this particular project.

13. Principal Investigator Signature

14. Co-investigator(s) signature(s)

15. Student signature

16. OC Administrative Head/Faculty Dean

All signatures must be obtained before submission of the proposal. Missing signatures will result in the proposal being sent back.

The Principal Investigator or the Faculty Supervisor (if an undergraduate student is involved) signature must be supplied.

All attempts should be made to contact the individuals who are required to sign the application form. However, if original signatures are not obtainable (e.g., the co-investigator is not available for signing), then faxes or email signatures will be accepted.

OC Administrative Head/Faculty Dean signature confirms that the Principal Investigator has the qualifications, experience and facilities to carry out the proposed research.

An OC sponsor is required for research being conducted at OC by researchers not employed at OC. The OC sponsor must be at the Dean or Director level.

17. Similar Application

Indicate if this, or a similar application, has been submitted to any other Research Ethics Board for review. If an application has been made, please provide the name of the institution, the date of the review, and the decision of the review board. If available, attach a copy of the approval certificate. If review by another Research Ethics Board is pending, please provide the expected date on which the proposal will be reviewed and indicate that approval is pending.

18. Graduate Studies

If the proposed project is being performed as part of a graduate degree program, please provide the required information.

19. Institution, Agency or Community Group Involved

Identify any other institution, agency, or community group involved in your research and provide a contact name and telephone number, if applicable. If OC personnel or students are being surveyed, a letter of approval is required from the appropriate Dean or administrative head.

20. Submission check list

Required Documents: 2 copies of the completed Application Form (one with original signatures) and all attachments and 2 copies of the full research proposal.

The application form and its attachments must be properly collated, and stapled or clipped together. Do not use covers, binders, or file folders. Copy **both** sides of two-sided pages. The copies may be submitted as two-sided documents. **The REB office will not check the content of each copy or collate attachments. Applications that are submitted without complete attachments will not be reviewed by the REB and will have to be resubmitted.**

Please assign a version date to all attached documents and note this in the right hand column of item #20 of the form. This version date must be included in a footnote on each page of the study documents.

The following list describes some of the documents that may be attached to the application. Please attach the documents in the order in which they will be used, i.e. recruitment letter, consent form, interview questions.

a) **Application form (required for ALL applications)** – The original (signed copy) must include the original signatures of the Principal Investigator, Administrative Head, and if this is research for a graduate degree, the signatures of the student and Faculty Dean (in place of the Principal Investigator's Administrative Head).

b) **Advertisement to Recruit Subjects** – This includes any type of communication (e.g., flyer, radio/television script, poster, newspaper ad, Internet message) that is directed to potential subjects for the purpose of recruitment. The purpose of this documentation is to ensure that the recruitment measures are appropriate and not coercive.

c) **Letter of Initial Contact** – This is the preferred method of recruitment when contact is initiated by the researcher rather than by the subject responding to an advertisement.

d) **Subject Consent Form** – Informed consent is documented by means of a written, signed, and dated informed consent form, following a process by which a subject voluntarily confirms his or her willingness to participate in a particular study, after having been informed of all aspects of the study that are relevant to the subject's decision to participate.

e) **Normal/Control Subject Consent Form** – This is a separate consent form for subjects who participate as controls in the research study (if needed).

f) **Parent/Guardian Consent Form** – The age of majority in British Columbia is 19; therefore, parental consent is normally required for anyone 18 years of age or younger.

g) **Remote Contact Form** – Interviews by telephone are discouraged by OC. Interviews may be conducted by telephone after making contact by mail or email and obtaining written consent. However, interviews where initial contact is made by random digit dialing or when written consent is not obtained, may be allowed. In these cases, complete and attach Form 3 "Remote Contact Form".

h) **Deception Form** – If the research depends on a temporary exception to the general requirements for full disclosure in the consent process complete Form 4 "Deception Form". Also read Article 2.1 of the TCPS. Where deception is involved, a written debriefing (or text for a verbal debriefing) must also be submitted in which the deception is explained to study subjects.

i) **Questionnaires, Tests, Interview Scripts, etc**. – Append copies of all W)-A7.2(mit-11(f)-e 0 T-(s)-2(.6

should be submitted concurrently to the OC REB and the agency. Please indicate whether a request for approval has been submitted to the agency or whether conditional approval by the OC REB must accompany a request to the agency for approval.

21. Project summary

Summarize the purpose, goals and objectives of the project in a concise and comprehensible manner with minimum use of technical language. Include: background, purpose, hypothesis/goals, and justification (scientific/scholarly validity, appropriateness of utilizing human subjects).

Purpose - This is the main reason that the study is being conducted and should include direct implications/applications of the research.

Hypothesis or Aim - This specifies the precise research question(s) and expected outcome(s) of the study.

All studies must have benefit in order to justify being conducted. You must provide a description of known or potential benefits to study subjects and/or society.

Describe the methodology and procedures to be used. Method is often intertwined with ethical considerations and thus a non-technical description of the procedures used (along with any citations) is requested. Procedures must be detailed sequentially. For studies involving qualitative techniques (e.g., interviews, questionnaires) a copy of all materials must be included with this proposal. In the case of a standardized scale or instrument, a description of its purpose as well as an explanation for why this particular scale/instrument was selected, must be provided. The Board will be assessing methodology but will not be undertaking peer review of the research. If the REB has significant questions or concerns about the methodology, it may bring in an expert to assist. The researcher may be contacted to recommend such a person. It should be remembered that the REB cannot approve a poorly-designed research project on ethical grounds since it would subject study participants to unnecessary testing.

If research is conducted by telephone, the researcher must complete Form 3.

22. Where will the research be carried out?

Describe the location(s) where the project will take place (e.g., community hall, school, home, university). The REB needs this information to determine what, if any, agency approvals are required. Indicate what level of privacy study subjects might expect during their participation.

23. How many subjects will be enrolled

When considering the number of individuals you wish to include, be sure that you recognize that while you may approach X number of people, the number who actually consent to participate may vary considerably. If there is a control group, you should determine what number/ratio would be methodologically sound. If there is no control group, please indicate 'No control group'.

24. Who is being recruited

Researchers must describe the criteria used to select prospective study subjects. Researchers are reminded that vulnerable groups may be more difficult to include but ought not to be rejected solely for this reason (e.g. aboriginal groups, minors, persons with disabilities, etc.).

In compliance with TCPS Articles 5.1(a), (b), 5.2 and 5.3, the selection of subjects must be considered equitable. TCPS Article 2.5 c states, "Individuals who are not legally competent

shall only be asked to become research subjects when the research does not expose them to more than minimal risks without the potential for direct benefits for them." The selection of subjects must take the following specific TCPS requirements into consideration.

a) The research, where practicable, should strive to achieve a demographically representative sampling, subject to the constraints of the research hypothesis/purpose;
b)

a) Your survey must be completely anonymous and you must not collect any personally identifying information such as name, address, telephone number, email address, student number, employee number, social insurance number or any other unique personal identifiers; and,
b) Your surveys must not collect any sensitive personal information such as medical conditions, medical care received, academic grades or details of academic performance, illegal activities, criminal history, personal finances, racial or ethnic origin, sexual orientation, religious or political opinions or associations, and opinions about named third parties.

If you wish to conduct surveys which collect sensitive personal information as described above or collect personal information in identifiable form, you must use a Canadian based service provider who stores the information in Canada.

Telephone Interviews: Research that is 'limited' (i.e., no other method of gathering data on the individual subject) to a telephone interview, where the subject does not have the anonymity of random selection, requires initial contact by letter or email. The letter or email must have all of the components of a consent form.

The REB will determine on a case-by-case basis whether the consent form needs to be signed and returned to the researcher before the interview takes place. The level of risk or invasiveness of the interview will be the main consideration. The researcher should provide justification for this approach and indicate whether the subject or the researcher will initiate the telephone interview. If the researcher plans to follow-up the consent form with a telephone call, the consent form should include a contact name and number for the subject to call to stop further contact.

Coercion: Provide a statement of the researcher's relationship, if any, to the subjects (e.g., treating physician, teacher, supervisor, etc.). Whenever the person doing the recruiting is in a position of authority over potential research subjects, special care needs to be taken. For example, whenever the relationship between the researcher and research subject (e.g., when the researcher is also a caregiver or teacher) is such that coercion could be perceived to be a factor, non-

contact information or any other detail about potential subjects without first obtaining permission from those subjects. Exceptions to this are reviewed on a case-by-case basis by the REB. The ideal process would involve providing the contact with a recruitment letter to show or send to potential subjects. This ensures that the information given out is accurate and consistent.

26. Exclusion of subjects from participation

Researchers should consider the various factors that may make it more difficult for the study subject to be representative of the target population and/or able to offer informed consent.
Provide justification for excluding subjects on the basis of such attributes as culture, language, religion, race, disability, sexual orientation, ethnicity, gender or age. Refer to TCPS Article 5.1.

27. Compensation or reimbursement

Researchers may wish to compensate study subjects for taking the time to participate in their research, e.g. by offering coffee or by refunding any personal costs incurred by the subject (bus or taxi fare) if presented with a receipt. One must be careful not to make this compensation a reward for participation. If study subjects are to be compensated, provide details of the amounts to be paid, the reason(s) for the payment(s), and the timing of payment(s).

Payments: Voluntary consent must be free of undue influence in the form of inducements. The amount or kind of payment should not be such that the subject will base his/her decision to participate on the potential material rewards.

The TCPS Article 2.4 states, "In research projects where subjects will be compensated, REBs should be sensitive to the possibility of undue inducement for participation, such as payments that would lead subjects to undertake actions that they would not ordinarily accept. REBs should pay attention to issues such as the economic circumstances of those in the pool of prospective subjects, and to the magnitude and probability of harms."

The REB will weigh the amount of compensation offered against the amount of time and inconvenience to the subject on a case-by-case basis. It is considered coercive and thus unacceptable to have payment depend on completion of the project. However, in many cases it would be considered acceptable to pro-rate the amount of compensation given to subjects who withdraw before completion.

Lotteries and Draws: As an incentive to participate in studies, researchers frequently offer study subjects a chance at a prize in a draw. If such a draw does not include those who decline to participate, technically it becomes a lottery and is illegal in British Columbia (without a license). This includes draws where the subject pays or 'barters' for a chance at a prize by completing some aspect of the research project. Consequently, researchers must ensure that participation in the draw is not contingent on participation in the research, and any subjects who withdraw must also have the opportunity to have their names included in such draws. The REB considers the use of draws as an acceptable incentive if the names of those who withdraw from the study are also included in the draw.

Confidentiality: Special care should be taken when offering compensation or prizes in a draw that the method of collecting payment or the prize or entering a draw does not compromise the confidentiality of the study subject.

28. Vulnerable populations as study subjects

If subjects in the study are considered members of a (potentially) vulnerable group, this must be identified. Children, institutionalized persons or others who are vulnerable are entitled, on grounds of human dignity, caring, solidarity and fairness, to special protection against abuse,

exploitation or discrimination. Ethical obligations to vulnerable individuals in the research enterprise will often translate into special procedures to protect their interests.

29. Problems/special issues with giving informed consent

through OC’s counseling department).

33. Potential benefits

All studies must have some benefit to either individual subjects or to society at large in order to justify being condu

Researchers must comply with the Tri-Council guidelines on this matter (Article 3.2).

Reportable Offences: Some research may involve an increased possibility of reports of child abuse. The Child, Family and Community Service Act of B.C. requires that anyone who has reason to believe that a child may be abused, neglected, or is for any other reason in need of protection, must report it to the Director or a designated social worker (Ministry of Children and Family Development).

The REB may require that a sentence be included in the consent form informing study subjects that reports or allegations of abuse must be reported to the proper authorities.

41. Publication plans

Provide information on any publication plans and explain any restrictions or limitations.

42. Future use of data

Describe any future use of the data beyond the conclusion of this research project and indicate whether subject consent will be obtained *now* in the current consent procedure or whether the subject will be contacted *later* to obtain consent. Either possibility must be described in the consent form. If consent is to be obtained now, future use of the data must be described in full in the consent form included with the current application. If consent for future use of the data is to be obtaine

d) Ethnography:

If the research involves studying people, those being studied have a right to know that they are being studied, what the research is about, what is required of them, and that they have a right not to be researched. Participant observation studies that do not meet the above standard are still possible as long as the relevant group approves the project. For example: spending a year in a remote indigenous community would normally require the approval of the community council or appropriate authority rather than the approval of each individual. The REB also acknowledges that in some cases it may not be possible to obtain the appropriate approvals prior to arriving at the research site and establishing relationships with members of the community. Fieldworkers need to be specific in their application by outlining their approach to obtaining approval either prior to, or once in, the field.

The REB recognizes that some anthropological fieldwork is necessarily exploratory in nature.

a consent form (i.e. age 13 - 18) should be provided with a consent form to sign. Regardless of competency due to age or ability, and in spite of authorized third party or parental consent, the investigator should not compel a subject to participate if it is clearly against his/her will.

Consent renewal: The TCPS Article 2.1 states, “Free and informed consent lies at the heart of ethical research involving human subjects. It encompasses a process that begins with the initial contact and carries through to the end of the involvement of research subjects in the project.” Thus, consent is an on-going process after the initial signing of the consent form and researchers should verbally confirm with study subjects that they are still willing to continue participating at each encounter during the study.

Describe the consent process – include information on who will ask for consent [e.g., the Principal Investigator, Co-investigator(s), and/or research assistant(s)].

Indicate how long subjects will have to decide on whether to participate. Note: the TCPS, Article 2.4 states, “Rushing the free and informed consent process or treating it as a perfunctory routine violates the principle of respect for persons, and may cause difficulty for potential subjects-6(t)-6.6(i)2.6(c)8.8(Td)nc subdtets-6(6.6(s)(pr)--2(-6(t)-6 n6(e of)-17.5(r)-5.9(es)-.6(c(i)2

APPENDIX 1: GUIDING ETHICAL PRINCIPLES

Taken from the Tri-Council Policy Statement, Ethical Conduct for Research Involving Humans

The approach taken in this framework is to guide and evoke thoughtful actions based on principles. The principles that follow are based on the guidelines of the Councils over the last decades, on more recent statements by other Canadian agencies, and on statements from the international community. The principles have been widely adopted by diverse research disciplines. As such, they express common standards, values and aspirations of the research community.

Respect for Human Dignity: The cardinal principle of modern research ethics, as discussed above, is respect for human dignity. This principle aspires to protecting the multiple and interdependent interests of the person – from bodily to psychological to cultural integrity. This principle forms the basis of the ethical obligations in research that are listed below.

In certain situations, conflicts may arise from application of these principles in isolation from one another. Researchers and Research Ethics Boards must carefully weigh all the principles and circumstances involved to reach a reasoned and defensible conclusion.

Respect for Free and Informed Consent: Individuals are generally presumed to have the capacity and right to make free and informed decisions. Respect for persons thus means respecting the exercise of individual consent. In practical terms within the ethics review process, the principle of respect for persons translates into the dialogue, process, rights, duties and requirements for free and informed consent by the research subject.

Respect for Vulnerable Persons: Respect for human dignity entails high ethical obligations towards vulnerable persons – to those whose diminished competence and/or decision-making capacity make them vulnerable. Children, institutionalized persons or others who are vulnerable are entitled, on grounds of human dignity, caring, solidarity and fairness, to special protection against abuse, exploitation or discrimination. Ethical obligations to vulnerable individuals in the research enterprise will often translate into special procedures to protect their interests.

Respect for Privacy and Confidentiality: Respect for human dignity also implies the principles of respect for privacy and confidentiality. In many cultures, privacy and confidentiality are considered fundamental to human dignity. Thus, standards of privacy and confidentiality protect the access, control and dissemination of personal information. In doing so, such standards help to protect mental or psychological integrity. They are thus consonant with values underlying privacy, confidentiality and anonymity respected.

Respect for Justice and Inclusiveness: Justice connotes fairness and equity. Procedural justice requires that the ethics review process have fair methods, standards and procedures for reviewing research protocols, and that the process be effectively independent. Justice also concerns the distribution of benefits and burdens of research. On the one hand, distributive justice means that no segment of the population should be unfairly burdened with the harms of research. It thus imposes particular obligations toward individuals who are vulnerable and unable to protect their own interests in order to ensure that they are not exploited for the advancement of knowledge. History has many chapters of such exploitation. On the other hand, distributive justice also imposes duties neither to neglect nor discriminate against individuals and groups who may benefit from advances in research.

Balancing Harms and Benefits: The analysis, balance and distribution of harms and benefits are critical to the ethics of human research. Modern research ethics, for instance, require a favourable harms-benefit balance – that is, that the foreseeable harms should not outweigh anticipated benefits. Harms-benefits analysis thus affects the welfare and rights of research subjects, the informed assumption of harms and benefits, and the ethical justifications for competing research paths. Because research involves advancing the frontiers of knowledge, its undertaking often involves uncertainty about the precise magnitude and kind of benefits or harms that attend proposed research. These realities and the principle of respect for human dignity impose ethical obligations on the prerequisites, scientific validity, design and conduct of research. These concerns are particularly evident in biomedical and health research; in research they need to be tempered in areas such as political science, economics or modern history (including biographies), areas in which research may ethically result in the harming of the reputations of organizations or individuals in public life.

Minimizing Harm: A principle directly related to harms-benefits analysis is non-maleficence, or the duty to avoid, prevent or minimize harms to others. Research subjects must not be subjected to unnecessary risks of harm, and their participation in research must be essential to achieving scientifically and societally important aims that cannot be realized without the participation of human subjects. In addition, it should be kept in mind that the principle of minimizing harm requires that the research involve the smallest number of human subjects and

APPENDIX 2: CLASS PROJECT GUIDELINES

The Research Ethics Board has developed the following guidelines for the review of class projects that require students to undertake projects that involve human subjects in questionnaires, interviews, testing, observations, video and audiotape, etc. These projects are usually developed by the instructor for teaching purposes (i.e. they are not developed independently by students as part of a research-based course).

1. The instructor should take the role of the Principal Investigator and submit a generic **Application for Ethical Review (Form 1)** for the class. It should summarize the instructions given to the class and include a list of the students, with a description of each student project, the sample population, the number of subjects, and the method of recruitment.

2. In the case of projects carried out at other institutions or agencies, written evidence of **agency approval** granting permission to carry out individual studies (e.g. school boards, etc.) must be obtained and a copy sent to the REB.

3.