



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.

Forms are revised periodically. Please be sure that you have an updated copy.

HUMAN SUBJECT INVOLVEMENT & SCOPE OF RESEARCH

"Research" involves the systematic investigation to establish facts, principles or generalizable knowledge.

Any research project (including pilot studies, exploratory studies, etc.) involving human subjects in procedures that involve potential invasions of privacy, which is carried out by a person employed by OC or enrolled in course-work at OC, must be reviewed and approved by the REB before the research begins. Research projects may involve asking subjects to participate in studies that use, for example, **questionnaires, interviews, focus groups, observation, secondary use of data, deception, testing, video and audio taping.**

The TCPS, 1998, Section 1.1, stipulates the following exceptions:

"Research about a living individual involved in the public arena, or about an artist based exclusively on publicly available information, documents, records, works, performances,

archival materials or third-party interviews, is not required to undergo ethics review. Such research will require review if the subject is approached directly for interviews or for access to private papers.

Quality assurance studies, performance reviews or testing within normal educational requirements are also not subject to review.”

Information gathering activities **may constitute research requiring Research Ethics Board approval when** they meet one or more of the following characteristics:

- The primary aim of the data collection is to produce conceptual knowledge or expand existing published theory.
- There is an expectation to share the results or findings within a professional community through publication, articles, conference paper, etcetera.
- Participants may be manipulated or exposed to certain conditions without their awareness as a part of their research participation.
- It involves the active participation of “at-risk” participants such as children or other vulnerable populations, or involves the collection of personally sensitive information.
- If it is possible to identify individual respondents so that confidentiality cannot be assured.

Information gathering procedures **may be classed as “in support of general administration of the College” when** they exhibit none of the above-noted characteristics, and

- The primary aim of the activity is to diagnose problems, identify appropriate solutions, provide advice for operation management, or assess performance.
- The data collection is primarily designed to affect the operations of the College simply through affirming satisfaction with the status quo or leading to quality improvements.

(Source: University of Manitoba guidelines)

SUBMISSIONS TO THE BOARD

Submissions must be made on the [Application for Ethical Review form \(Form 1\)](#). Researchers should refer to the [Guidelines for Developing an Informed Consent Form \(Form 2\)](#), which includes a suggested template) when preparing any consent forms. Because these documents have been designed to deal with a range of possible projects, not every question is applicable to every project. Applicants should simply enter 'n/a' when this situation occurs.

Submissions should be forwarded to the REB Office, Centre for Learning building, E-416, KLO Campus. The Board Secretary will assign a number to your research proposal and you will be notified of the date on which the REB will review the application.

To help you ensure that all the required items are incorporated into any consent form or questionnaire, two checklists are included in this Application Form. Please make sure that all items in the checklists are dealt with.

TURN-AROUND TIME

The REB meetings are usually held once a month, except July and August. The deadline for submitting an application and its attachments to the Research Office is two weeks before the meeting (approximately 14 days). Please refer to the web page for up-to-date schedules, at <http://www.okanagan.bc.ca/about/reb.html>.

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 party (see below), initial telephone contact may be allowed. If your study involves such contact, you must also complete a Remote Contact Form (Form 3).

THIRD PARTY RECRUITMENT

When subjects' 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 subjects for permission to release their names to the researcher. This may also be done by asking the third party to distribute an introductory letter describing the study, with details on how to contact the researcher if they are interested in participating. Details of how third party recruitment will be accomplished and copies of any letters sent to either the third party or to the subject via the third party must be provided with the application. If the researcher already has some form of contact with the subject (e.g. a nurse's contact with a patient) the circumstances of that contact must be fully described.

DECISIONS ARISING FROM THE REVIEW

The outcome of the review of the Application will be one of the following four decisions: approved, provisionally approved, deferred, or not approved. Note that research cannot begin until a Certificate of Approval has been issued. The notification of the decision in writing to the investigator is consistent with TCPS Article 1.9.

- a) **Approved** – As required by the TCPS the Certificate of Approval will be issued for a term of one year.
- b) **Provisionally approved** – Some concerns need to be addressed before approval is given. The REB authorizes the Chair to grant approval when the concerns addressed to the investigators in the REB review response letter (i.e., the provisions) have been satisfactorily addressed.
- c) **Deferred** – Based on the documentation provided, the REB is unable to make a final decision. The decision is deferred until such time as the investigators submit the supplementary information or documentation as specified by the REB review response letter.
- d) **Not Approved** – According to TCPS Article 1.10 on Reconsideration, “Researchers have the right to request, and Research Ethics Boards have an obligation to provide, reconsideration of decisions affecting a research project.”

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 collected/analysed on OC premises, should not use OC resources, and should not indicate an association with OC when results are publicly disseminated. If research data collected through outside professional activity is disseminated in the public domain but in association with OC, ethics approval is required. It is advisable to request ethics approval if there is a possibility that the information collected from an outside professional activity will be used directly for the same (or similar) research purposes within OC in the future.

Examples of outside professional activities include: project performed as part of an independent consulting contract between the OC faculty/staff member and another agency/institution or projects conducted as part of a graduate program where the OC faculty/staff member is registered as a graduate student at another university. In the latter case, ethical review of the

project is the responsibility of the university at which the OC faculty/staff member is registered as a student. If there is a question as to whether a research project is an outside professional activity or part of the researcher's OC activities and duties, the REB will determine how the research should be classified.

In cases where a faculty/staff member is still working at OC whilst enrolled in a graduate program elsewhere but is performing the research purely on their own time and outside of OC, the REB requests that copies of the following documents be submitted: (1) the Application for Ethical Review to the other institution (on that institution's application form), (2) any comments or feedback supplied by the other university's REB, and (3) the Certificate of Ethics Approval. The accompanying cover letter should clearly indicate that the faculty/staff member will be performing the study as a student of another university, not as an OC faculty member, and that the research will be conducted on the researcher's own time, without the use of OC resources. The REB will review the project purely to ensure that OC is not in fact involved. If the REB has any comments about the proposal, feedback will be provided to the applicant. A Certificate of Ethics Approval will not be issued by the OC REB.

INSTRUCTIONS AND INFORMATION ON HOW TO COMPLETE THE APPLICATION FOR ETHICAL REVIEW FORM

Numbers listed below correspond to the box numbers on the Application Form. Point form responses are acceptable, **so long as their meaning is clear. Please minimize the use of technical language**, to ensure that the application is clear and understandable to the REB.

1. Principal Investigator (or Student Supervisor)

The Principal Investigator must have an OC Faculty Appointment.

If the research is for an undergraduate degree, the undergraduate student's supervisor must be listed as the Principal Investigator. The Faculty Supervisor will be held accountable by OC for the ethics of the research. It is also the Faculty Supervisor's responsibility to inform the Department Head and the REB of any change to the application or supporting documents during a research study.

Anyone not affiliated with OC wishing to conduct research at Okanagan College (without involving a member of the OC faculty as a co-investigator) must submit an application for ethical review on the appropriate OC forms. A student researcher should list his/her faculty advisor from the home institution as the Principal Investigator. The application should include a cover letter indicating that it is a non-OC affiliated study. A letter of permission from the OC department or administrative unit responsible for the space or resources to be used for the research project should also be submitted.

Note: all correspondence will be directed to the Principal Investigator. It is the responsibility of the Principal Investigator to advise any co-investigator(s) or student(s) about the status and outcome of the REB review.

2. OC Department/Faculty

The name of the department of the Principal Investigator

3. Phone Number

4. Fax Number (if easily available)

5. E-mail address

6. Campus address

The appropriate contact information for the Principal Investigator

7. Co-Investigator(s)

8. Student(s)

If there is more than one investigator or if there is a student involved in the investigation, then their name(s) should appear here.

If the research is conducted by an undergraduate student for a course-based project, please do not use this form but complete an Application for Ethical Review of an Undergraduate Student Research Project (Form 7) instead.

9. Granting Agency/Source of funding

If you are applying for or are receiving funding from any source to support the research proposed (e.g., SSHRC or NSERC), please put the appropriate information here.

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 relevant study materials. Indicate whether the questionnaire is a standardized, validated instrument or whether it is in development. If the latter, please send a copy of the finalized questionnaire to the REB office as soon as it is available. Please ensure that qualitative data collection tools are also included, when appropriate. Please note that researchers are expected to have permission from the authors to use copyrighted tests, although they do not need to provide evidence of this for the REB.
- j) **Cover letter for the questionnaire** – If the study is limited to a questionnaire that is completed by the subject, a covering letter may be used in lieu of a consent form, provided it includes essentially the same information as a consent form, plus a sentence that states that "If the questionnaire is completed, it will be assumed that consent has been given" (see box 49). This cover letter should be printed on OC letterhead. If a study involves other procedures and a consent form, a covering letter is not required, unless the questionnaire is completed or sent to the subject at a later date.
- k) **Other documents** – These are required when permission must be obtained from the appropriate organization (such as a school board, hospital, other university) to undertake the study at a particular site. Written proof of agency approval (to use the premises or to access clients, patrons or patients) is required for projects carried out at other institutions. If agency approval cannot be obtained without prior approval of the OC REB, a letter of conditional approval will be issued for submission to the agency if all other aspects of the application are satisfactory. Whenever possible, applications

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) If the proposed research involves subjects who are vulnerable 1) because they are not competent to give a legally or ethically valid consent, or 2) because of their relative social or economic powerlessness, the research must never intentionally or inadvertently increase or exploit this vulnerability, nor should they be excluded from research which is potentially beneficial to them as individuals, or to the group that they represent.

25. Recruitment process

The source of subjects and the manner in which they will be recruited must be described in detail. Researchers should be aware of the potential perception of conflict of interest and concerns over confidentiality and risk especially if he or she is requesting his or her own students to participate. Surveys conducted by mail must contain a cover letter to the questionnaire and this should be attached to the application. The covering letter should be typed and on OC letterhead indicating the researcher’s department. In case of telephone or door to door surveys, the researcher should ensure that prospective subjects receive advance notification about the study enabling them to verify the study’s authenticity if they so choose. For studies involving the recruitment of students and/or teachers from local school systems (i.e., elementary and/or secondary schools), researchers must receive consent from the school board and the principal prior to any request for student or teacher participation.

Researchers are reminded that certain groups may experience undue pressure to volunteer as research subjects (e.g., students, developmentally challenged, incarcerated individuals etc.) thus care must be taken to ensure that the research is methodologically and ethically sound.

- a) Describe how you will gain access to names, addresses, telephone numbers, or email addresses of potential subjects.
- b) Attach copies of any recruitment materials, such as letters, advertisements, flyers, radio or television scripts, or Internet messages.
- c) Indicate where subjects will be recruited (e.g., hospital, clinic, school).
- d) OC does not support initial contact by telephone, except under unusual circumstances where initial contact is made by random digit dialing (see Form 3).
- e) Ethnographic fieldwork may require very different means of contacting people. Please describe how you plan to initiate relationships with the people you will be studying.

Online Survey: If an online survey tool is being used, the researcher must determine where the data is being stored. Data storage in the US is strongly discouraged. The BC Freedom of Information and Protection of Privacy Act states that personal information must be stored only in Canada unless the individual has identified the information and has consented to it being stored elsewhere.

Email addresses and contact information about students are considered personal information and must be protected.

The OC REB will allow use of foreign service providers of WEB survey tools only under the following conditions:

- 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-coercive means for inviting participation should be used. Can the subject/student refuse to take part in the study without the investigator/teacher knowing? A typical example would be posting notices to invite volunteers from the entire group concerned (e.g., the whole student body, rather than a specific class, or all employees of the institution).

Third Party Recruitment: In some studies, the researcher requires access to subject data (names, addresses, relatives, etc.) to invite their participation in the proposed research, or to extract information from a third party's records (e.g. often the primary caregiver holds the personal patient information). In such cases, permission to use the data must be obtained from the subject by the third party before access to such information is permitted. The third party must ask the subjects for permission to release their names to the researcher. This may also be done by asking the third party to distribute an introductory letter describing the study, with details on how to contact the researcher if they are interested in participating. Details of how third party recruitment will be accomplished and copies of any letters sent to either the third party or to the subject via the third party must be provided for review by the REB.

Snowball Sampling: Snowball sampling involves contacts or subjects known to the researcher facilitating the recruitment of other potential subjects. This process must conform to the third party recruitment policy described above. Contacts should not give researchers the names and

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 'barter' 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

Researchers must consider whether prospective subjects will have difficulties giving consent, either because of a lack of understanding (e.g., a young child) or because of other factors (short time allotted). If language is a concern, the researcher may wish to consider having the project translated if appropriate.

30. Unable to give full consent

While children cannot give fully informed consent, they should be informed as much as possible and allowed to express assent prior to the commencement of any study. Special care should be taken to ensure that the child is excused from the study if he or she shows any signs of distress or boredom. Parental or guardian consent must normally be given in writing and the researcher and parent should both retain copies of this letter. Information in the consent letter must contain all the features described in the consent form and should include any pertinent details to assure the safety and security of the child within the study (i.e., protecting anonymity and confidentiality).

31. Estimate of risk

Known and anticipated risks to subjects must be identified for each procedure, test, interview or any other aspect of the study. Risks may be physiological, psychological, emotional, economic or social in nature. Note that risks may also include social harms such as breach of confidentiality, social stigmatization, threats to reputation, and psychological harm. Researchers are required to identify risks as either minimal or greater than minimal risk. The standard of minimal risk is commonly defined as follows: "If potential participants can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the participant in those aspects of his or her everyday life that relate to the research then the research can be regarded as within the range of minimal risk. Above the threshold of minimal risk, the research warrants a higher degree of scrutiny and greater provision for the protection of the interests of prospective participants." (TCPS, Section 1, C1).

Describe any strategies that are in place to minimize or manage the risks for subjects and other affected individuals.

Sensitivity to cultural issues: Researchers have two obligations which are frequently in conflict: the requirement of describing experimental populations in enough detail that others can understand the general applicability of findings and the ethical obligation to avoid unfairly stereotyping vulnerable segments of a population – or unwittingly providing data which allow others to unfairly stereotype them. Recent developments in meta-analysis make the latter particularly perilous.

Consequently, researchers who collect data on such demographic features as race, birthplace, gender, and sexual orientation must justify the need for collecting such data and must assure the Board that these data will not be analyzed in such a way that unfair stereotypes may be drawn and that reports will not allow others to use the data to create unfair stereotypes.

32. Discomfort or incapacity

If there are any physical or psychological discomforts or a perceived power imbalance between the researcher and the subjects (or instructor/students), the researcher should express what these are and how they will be dealt with (e.g., providing information about services available

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 conducted.

Specify the potential benefits to the study subjects or society. If there are no direct benefits to subjects, state this explicitly. If any specific benefits cannot be assured, but may be hoped for by the subject, state explicitly that the subject may or may not benefit from participation in the study.

34. Time required of subject to participate

Researchers must provide the approximate amount of time required for a subject's participation. If there is more than one session involved, the individual should be made aware of both the total amount of time involved as well as the amount of time involved in each session (e.g., 2 – 20 minute sessions over a 2 week period, for a total of 40 minutes).

Ensure that you also include this information in the consent form and that the amount of time stated is consistent in the application, recruitment letters or posters, and consent form.

35. Time for control group

See note 34 above.

36. Access to data

Researchers should make clear who will have access to raw data and aggregate data. Give the names (if known) of those who will have access to the raw data, which may include information that would identify study subjects. Research subjects must also be told in the consent form who will have access to his/her data and what use will be made of it, either now or in the future.

37. Maintaining confidentiality

Researchers must provide details on how confidentiality and anonymity will be maintained, for example, by using code names or anonymous submissions. Ideally, all identifiers should be removed. If there is the possibility of some information becoming public that could lead to the identification of the study subjects, reasons must be provided and weighed against any other alternative method of collecting data that would protect identities. Web based questionnaires must use encryption software.

Section 3 of the TCPS states, "As a general rule, the best protection of the confidentiality of personal information and records will be achieved through anonymity."

The terms 'anonymity' and 'confidentiality' are often used inappropriately in the application form and in consent documents. The REB has provided the following definitions:

Anonymity: The research subject is only anonymous if the data do not include any identifiers, codes, or unique information that can be used to identify the subject. If the subject has participated in a face-to-face interview, he/she is not anonymous. On the other hand, the data may be anonymous if someone other than the researcher(s) has removed all identifiers from the data, or the key linking the subject to code numbers or pseudonyms is destroyed.

A subject might be said to be anonymous: a) as the result of database linkages, where the researcher receives anonymous data only, or b) if the subject is completing a questionnaire that

requires absolutely no identifying information, and he/she has not been recruited because of membership in a group (i.e. of patients, culture, religion, student body).

It is usually more appropriate to promise confidentiality to a subject, than to promise anonymity.

Confidentiality: The raw data may include the name and/or other identifiers, such as a code or membership in a group, which can be used to link the data to the subject's name. The research team will have access to this information, but it will not be included in the final reports of the research, nor will anyone other than those specified in the consent form be given access to the data. If subjects wish to have their comments attributed, this should be specified in the consent form.

Attribution: Interview subjects may prefer to have their comments attributed to themselves in a publication rather than to remain anonymous to the reader. The REB recognizes and accepts this possibility, provided that there is no danger to the subject and that it is specified in the consent form.

Focus Groups: Investigators should note in the consent form that only limited confidentiality can be offered in focus groups, as they cannot control what other participants do with the information discussed. For example include as sentence that says something like, "We encourage all participants to refrain from disclosing the contents of the discussion outside of the focus group; however, we cannot control what other participants do with the information discussed."

38. Withdrawal

If a subject withdraws from the study, indicate what will happen to his/her data. If the data from a withdrawn subject will be used in any way, explain why and how.

39. Storage and disposal of records and data

Researchers must ensure that the data collected are properly handled and protected and that the data are appropriately disposed of in a timely fashion.

Study documents that include subject data, for example: interview transcripts, completed questionnaires, and researcher's notes, must be kept in a locked filing cabinet. Computer files must be password protected. Confidential information must not be collected or exchanged via email.

Data should be stored for at least 5 years, but it may be retained for a longer period provided that it is stored securely. OC has no explicit requirement for the shredding of data at the end of this period; however destruction of the data is the best way of ensuring that confidentiality will not be breached. Please note that the responsibility for the security of the data rests with the Principal Investigator.

In some cases, data are of such value that they should not be destroyed. For example: oral history interviews with community elders. In these cases please describe your plans to preserve this material. The consent process should outline these plans and describe how and when it may be appropriate for others to have access to this information.

40. Access to data by outside persons or agencies

Identify any individuals or agencies outside of the Research group that may have, need, or desire access to the data. Provide details regarding what information will be made accessible, what is the justification for this access and what are the risks of allowing this access.

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 obtained later, full details, including the consent form, must be submitted to the REB in a new Application for Ethical Review, along with the new research proposal, and approval of this new proposal must be granted before the research begins.

Ethnography: The REB acknowledges that in the case of ethnographic field notes and interviews, researchers cannot be expected to know all the uses they plan to make of the data. The REB also understands that attempting to get informed consent many years later may place an undue burden on the researcher and may become impossible. Therefore, researchers should inform the peoples they are studying of the potential for future use of the data during the consent process.

Secondary Use of data: The Tri Council Policy Statement (Article 3.2) defines secondary use of data as, “the use in research of data contained in records collected for a purpose other than the research itself. Common examples are patient or school records or biological specimens, originally produced for therapeutic or educational purposes, but now proposed for use in research.”

43. Debriefing and feedback

Whenever possible, an attempt should be made to advise study subjects of the findings or results of the research in which they participated (see the TCPS “Guiding Ethical Principles” in Appendix 1).

44. Involved in Consent

If the research project involves any of the listed procedures, please check all that apply.

The methods described below are included here because they represent problems in obtaining free and informed consent. ***The REB will evaluate each application on a case-by-case basis; the comments below should be considered as guidance only; they are not models which bind the Board.***

The TCPS states a preference for written evidence of free and informed consent, therefore any exception must be fully explained and justified to the REB.

a) Action Research:

There are many possible definitions of action research but the core of AR is scientific social research which is participatory and practice-oriented, which aims to find solutions to social problems and to emancipate individuals and groups confronted with such problems. There is a cyclical process of researching, learning and putting what is learnt into practice. As such, it is a complex series of processes, predominately but not exclusively drawing upon qualitative approaches to research. AR attempts to break down the distinction between the researchers and the researched. Research is seen not only as a process of creating knowledge, but simultaneously, as education and development of consciousness and of mobilization for action. Participatory Action Research is a process involving: systematic investigation, education of all participants, action as an outcome, and community ownership and control.

Complex relationships exist between the researcher and participants in AR. When the relationship involves individuals of lesser power or status than the researcher, such as students, employees, inmates or clients, there is a potential for coercion – researchers should be sensitive to this power differential and avoid any possibility of it leading to coercion.

b) Data Linkage/Secondary use of data/Use of confidential information:

Data linkage, secondary use of data or use of confidential information for research purposes requires review and approval by the Research Ethics Board.

- i) **Anonymous data:** Use of previously collected research data in existing databases on anonymous individuals may receive minimal risk review.
- ii) **Identifiable data:** If identifying information is involved, the researcher must satisfy the REB that:
 - identifying information is essential to the research,
 - appropriate measures are taken to protect the privacy of the individuals and confidentiality of the data, and
 - the individuals have not objected to secondary use.(Please read TCPS articles 3.2 and 3.3).
- iii) **Consent:** If there is a possibility that published data from the research could be linked to individuals, the researcher should propose a strategy for obtaining consent or otherwise informing the subjects. (See TCPS article 3.4)

c) Deception:

Deception undermines informed consent. Research that involves deception requires completion of Form 4 and justification of the deception. Only research that meets the requirements of Article 2.1c of the TCPS will be exempted from full disclosure at the time of consent.

If your research project involves deception, you must indicate why you believe (a) that deception is necessary to achieve your research objective, (b) that the benefits of the research outweigh the cost to subjects, (c) that there will be no permanent damage as a result of the deception, and (d) how you will debrief subjects at the end of the study (see Form 4).

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. Research methods may need to be altered in the field and information gathered may fundamentally alter the focus of the research. Much anthropological research is based upon long-term relationships developed between the researcher and the community being studied and will therefore evolve over time. Also, the demands of the collaborative research model are such that researchers planning to undertake this type of research cannot have a defined agenda before establishing relationships with the peoples with whom they intend to work.

The researcher should describe the type of consent process he/she intends to use in item #47 and explain why it is the most appropriate method. For example, an oral consent process is clearly necessary in oral cultures, with illiterate subjects, or where a formal document is perceived as a risk, a lack of trust, or an insult. In the application for ethical review the researcher must, where possible, demonstrate knowledge of the community and its expectations regarding consent and the behaviour of the researcher. If this is not possible, the researcher should outline how he/she plans to determine the appropriate form of consent once in the field.

In the particular situation of ethnographic studies involving First Nations subjects, researchers should read Section 6 of the TCPS. This section is not policy but is to be considered as a starting point for discussions of working with aboriginal peoples. Researchers applying to the OC REB must be clear about the approach they are taking and the contacts they have already made with the communities or people.

e) Focus groups or Interviews:

Interviews are defined here as those that involve an interview with an expert in a similar position to the researcher (e.g., an academic, politician, owner or executive of a company, head of an NGO, or president of an association or union) and which are designed to obtain factual accounts of an event, a procedure, a process, history, and so forth, where there is minimal or no risk to the interviewee.

Information about the interview may be provided in advance by telephone or written contact (depending on the options available in a foreign country) or at the time of initial personal contact. If the interviewees agree to be interviewed, consent may be assumed, but they should be explicitly asked if they are agreeable to be interviewed about the subject before the interview begins. If possible and with permission of the interviewee, this question and response should be taped.

Article 2.1b of the TCPS states a preference for written evidence of free and informed consent, but “for some groups or individuals, a verbal agreement, perhaps with a handshake, is evidence of trust, and a request for a signature may imply distrust. Nonetheless, in most cases a written

statement of the information conveyed in the consent process, signed or not, should be left with the subject”.

If the focus group or interview involves study subjects who belong to a vulnerable population (e.g. minors, company employees, patients) or if there is some slight risk to study subjects in participating, written consent must be obtained.

Describe a consent process in item #47 that ensures that the interviewee(s) or focus group member(s) is fully informed. This may involve written or oral consent. Where oral consent is appropriate, the researcher should make a contemporaneous journal entry of the event and circumstances or audiotape the event.

f) Observation:

Article 2.3 of the TCPS states:

“REB review is normally required for research involving naturalistic observation. However, research involving observation of participants in, for example, political rallies, demonstrations or public meetings should not require REB review since it can be expected that the participants are seeking public visibility”.

“Naturalistic observation is used to study behaviour in a natural environment. Because knowledge of the research can be expected to influence behaviour, naturalistic observation generally implies that the subjects do not know that they are being observed, and hence can not have given their free and informed consent. Due to the need for respect for privacy, even in public places, naturalistic observation raises concerns of the privacy and dignity of those being observed. These concerns are accentuated if, for example, the research records permit identification of the subjects, or if the research environment is staged.”

A description of the nature of the activities, the environment, and the method of recording the activities to be observed should have been provided in item #23 of the form. If the observation does not allow for the identification of the subjects, it will be regarded as minimal risk. If individuals will be identified you must justify the need for this. If consent is required, describe how that will be obtained in box #47.

g) Questionnaires:

Append copies of all questionnaires. See also guidance notes 20 (h and i) and 49.

h) Remote contact:

Telephone or internet contact alone makes it impossible for a signed record of consent to be kept. If the research involves remote contact of subjects, please complete a Remote Contact Form (Form 3). See also guidance note 26 - 28 on recruitment of subjects.

i) Audio- or Videotaping:

If any subjects in a research setting which is videotaped decline to participate, researchers must take extra care to protect the rights of non-participants. On the one hand, it is unfair to require non-participants to sit outside camera range if this also excludes them from participating in the activity or marginalizes them in some other way. On the other hand, subjects' rights not to take part in the research must be respected.

In any case, electronically distorting the facial features of non-participants does not honour the subject's wish not to participate. It is not a matter of non-identification but a matter of non-participation.

45. Informed consent

Indicate who will give consent.

Consent for minors: The age of majority in British Columbia is 19 years of age and parental consent is required for subjects younger than 19. The REB can make an exception, but the investigator must provide adequate justification in the Application for Ethical Review (e.g., the child no longer lives with parent or guardian, the benefits to the child outweigh the risks, there is no invasion of privacy or sensitive issue involved, etc.).

Written parental consent is normally required for research in schools and an opportunity must be presented either verbally or in writing to the student to refuse to participate or withdraw at any time. A copy of what is written or said to the student must be included for review by the REB.

The REB considers minors attending University who are 17 to 18 years of age to be emancipated adults for the purposes of low risk research. Parental consent will generally only be required if the research study is not low risk or represents an invasion of the family's right to privacy. In either case, justification must be provided in the Application for Ethical Review.

Consent for incompetent subjects: The Principal Investigator must judge the potential subject's ability to consent on his or her own behalf, in all subjects, in all research projects, regardless of age.

Incompetent subjects should be given information and involved in decision making to the extent possible. See the related discussions in the TCPS (Articles 2.5, 2.6, 2.7). The OC REB may request that a written assent document accompany the consent process, depending on the nature of the project and the age or ability of the target population.

TCPS Article 2.5 states, "Subject to applicable legal requirements, individuals who are not legally competent shall only be asked to become research subjects when:

- a) The research question can only be addressed using individuals within the identified group(s);
- b) Free and informed consent will be sought from their authorized representative(s); or
- c) The research does not expose them to more than minimal risks, without the potential for direct benefits to them."

TCPS Article 2.6 states, "For research involving incompetent individuals, the REB shall ensure that, as a minimum, the following conditions are met:

- a) The investigator shall show how the free and informed consent will be sought from the authorized third party, and how the subject's best interests will be protected.
- b) The authorized third party may not be the investigator or any other member of the research team.
- c) The continued free and informed consent of an appropriately authorized third party will be required to continue the participation of a legally incompetent subject in research, so long as the subject remains incompetent.
- d) When a subject who was entered into a research project through third-party authorization becomes competent during the project, his or her informed consent shall be sought as a condition of continuing participation."

Assent: Assent is to concur with the decision of another whereas consent is to provide permission. Parental consent is required for research with children under the age of 19; assent would be required from the child. Children old enough to understand the concepts described in

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. The time required for the free and informed consent process can be expected to depend on such factors as the magnitude and probability of harms, the setting where the information is given (e.g., hospital or home) and the subject’s situation.”

46. Consent checklist

Please refer to Form 2 for guidance in developing an informed consent and for a sample format of a consent form.

Note that the list under item 46 contains the desired elements for informed consent. Ensure that your consent form contains all of these elements, where applicable. If any element is NOT included or NOT APPLICABLE, you should provide an explanation for this in Box 49.

47. Questionnaire checklist

It is expected that any questionnaire/survey will contain the information described in this list. If any element is NOT included or NOT APPLICABLE, you should provide an explanation for this in Box 49.

48. Conflict of interest

Provide information on any personal benefits that any researchers participating in this project will receive.

The REB needs to be satisfied that study subjects are informed of conflict of interest matters in the consent form. Note that “immediate family members” includes partners and children (whether living in the household or not). The REB does not require that the investigator identify holdings in managed mutual funds to be declared in the conflict of interest statements.

49. Additional Information

Provide any additional information that may assist the REB in reaching their decision.

Forms: Researchers must complete all forms as required and ensure that all details and information have been provided. Deviations from the forms are not permitted except in extraordinary cases.

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 the smallest number of tests on these subjects that will ensure scientifically valid data.

Maximizing Benefit: Another principle related to the harms and benefits of research is beneficence. The principle of beneficence imposes a duty to benefit others and, in research ethics, a duty to maximize net benefits. The principle has particular relevance for researchers in professions such as social work, education, health care and applied psychology. As noted earlier, human research is intended to produce benefits for subjects themselves, for other individuals or society as a whole, or for the advancement of knowledge. In most research, the primary benefits produced are for society and for the advancement of knowledge.

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. A standard procedure should be established for the class to follow with respect to informed consent, explanations to the subjects, right to withdraw without prejudice, etc. A copy of the **consent form** to be used by the students must be included with the instructor's Application for Ethical Review form for review by the REB. The REB recommends that the instructor have his/her students complete an Application for Ethical Review form as part of each instructor's mechanism for evaluating the ethical acceptability of the student's projects. These need not be submitted to the REB for review.
4. The instructor must retain all forms related to approving the ethical acceptability of each student's project for a period of two years.
5. If the student is also a health care professional (e.g. social worker or counselor) who chooses to do a research study that involves clients or patients, the student **must** complete an Application for Ethical Review form. The instructor should attach these to the 'generic' Application for Ethical Review form for the class project and forward to the REB for review.
6. The REB meets once a month, except in July and August. The deadline is two weeks before the meeting. Although the REB attempts to have a turnaround time of three weeks from the submission deadline, delays can occur if revisions to the study, consent form and other associated materials are required. Therefore, it is advisable to submit the Application for Ethical Review as far in advance as possible.
7. If you need assistance, please contact the REB Secretary at (250) 762-5445, Local 4561, or reb@okanagan.bc.ca.