



RESEARCH ETHICS BOARD
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Protocol #: _____
FORM 2

Guidelines for Developing an Informed Consent for Participants to Participate in a Research Project or Experiment

Guidance Notes:

This document is a tool to assist you in writing your own consent form. The final responsibility for ensuring that the consent form is clear and comprehensive is yours. Please, however, feel free to contact any member of the Research Ethics Board at reb@okanagan.bc.ca or for advice or assistance.

Presentation Style:

- Use a font size no smaller than 11 point.
- Use headings, small paragraphs and spaces between the paragraphs
- Use simple lay language - explain technical terms and jargon. Try to achieve a readability score at the grade 8 level. In Microsoft Word you can display the Flesch-Kincaid Grade Level Score by accessing Review/Spelling & Grammar/Options and by checking Show readability statistics.
- Write out all acronyms the first time they appear on each page.
- Number the pages and format as page # out of total number of pages (e.g. 1 of 3, 2 of 3, 3 of 3, etc.)
- Include a version date in the footer of every page of the consent form.
- All information required from the participant must be included in the informed consent form. Do not use attachments or additional information forms.
- The consent form submitted for review should be in its final form (as it will be seen by the participant), **including letterhead**. Photocopied letterhead is acceptable.
- Spelling and grammar must be corrected before the consent form is submitted for review.
- The consent form should be written in the second person. Use 'you' not 'I'.
- If revisions to a consent form are required after OC REB review (whether originating with the investigators or sponsor, or requested by the Research Ethics Board), please highlight these changes on the amended version and remember to change the version date.
- Any changes to the application **or** consent form must be approved by the OC REB before research begins or continues.

Contents:

Researchers should supply the following information in ordinary language, explaining any crucial/technical terms and avoiding jargon. If any item is obviously irrelevant, it need not be included. If items have been deleted, researchers should inform the Research Ethics Board either in an accompanying cover letter or in the Application for Ethical Review (Form 1). ***Please note that a sample consent form can be found on page 4 of this document.***

- Description of the purpose of the research.
- Description of the research design and an explanation of all procedures.

- Detailed description of procedures regarding participation and time commitment for participant. Include the specific time and location(s) involved.
- Description of the likelihood of any discomfort and/or inconvenience associated with participation, any known or suspected short and long-term risks and benefits, and factors which might lead to refusal to participate.
- Description of any financial cost that the participant may incur as a condition of, or because of, participation in the research. Description of any remuneration that the participant may receive.
- Description of how confidentiality will be protected. This section is to include a description of the degree of confidentiality that will be maintained; what information will be stored; how this information will be stored (e.g., audio, computer disks, etc.); procedures for security; who will have access to the data collected; description of how data will be disposed of; future use of data and how confidentiality and/or anonymity will be maintained.
- Description of how participants will receive updated information during the course of the research.
- Description of how the research will be used (e.g. presented at conferences, published work, etc.).
- Any audio/visual data or representation requires an additional waiver to be signed by participants.
- **For studies involving children with parental/guardian consent:** a statement that the investigator will, in addition to obtaining parental consent, explain to the child the nature of the research and his or her involvement and will seek the child's ongoing cooperation throughout the project.
- Copies of the results of this study, upon its completion, may be obtained by (*Investigators to complete_____*).
- **On-line 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.

The email addresses and contact information of 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 that collect any sensitive personal information as described above, or collect personal information in identifiable form, you must use a Canadian-based service provider that stores the information in Canada.

Recommended statements to be included in consents:

- You understand that you may refuse to participate or withdraw your participation in this project at any time without consequence.
- Your signature on this form indicates that you understand the information provided regarding this research project including all procedures and the personal risks involved.
- You voluntarily agree to participate in this project as a participant.
- Your participation in this project is in no way related to your employment contract or to your status as a patient, client or student (where applicable). *(Investigators – please choose one).*
- You understand that your identity and any identifying information obtained will be kept confidential.
- If you have any questions about the project, you may address them to the chief researcher _____, at (telephone or email), _____
(Investigators – please insert information).
- If you have any complaints about the project, you may contact the researcher’s supervisor _____, at (telephone or email), _____
(Dean/Chairperson/Faculty Advisor: Investigators – please choose one as appropriate).
- If you have any questions or concerns about your treatment or rights as a research participant, you may contact the Chair of the Research Ethics Board through the Office of Research Services, telephone number (250) 762-5445 (local 4525).
- This project has been reviewed and granted a certificate of approval by the OC Research Ethics Board.
- You will receive a copy of this signed consent form.

Name of study participant (Please Print): _____

Participant’s signature _____ Date _____

Investigator and/or Delegate’s signature _____ Date _____

You agree to have audio/visual data or other representation _____(describe) collected which entails _____ and will be used for _____ and will be destroyed by _____ (how and when)

Signature _____ Date _____

(Researcher to delete this audio/visual waiver if not applicable)



Your Department Name
Address

Informed Consent Form
[Title of Study]

Principal Investigator: Be sure that 'Principal' is not misspelled 'Principle'. Name, OC dept, contact telephone number, and e-mail address. Also, note that the Principal Investigator must have an OC Faculty appointment. Students must include the name and telephone number of their Faculty Supervisor/Advisor.

Co-Investigator(s): Name, OC Department, Institution, contact telephone number and e-mail address. OC students should identify themselves as such and include their department. If the research is for a graduate degree, a statement to this effect must be included and also clearly indicate whether it is part of a thesis (public document) or graduating essay (semi-public document). The participant must be informed of what use will be made of the information and who will have access.

Sponsor(s): Name of company(ies) and/or granting agency(ies) that is (are) supporting the research study.

Introduction:

Okanagan College subscribes to the ethical conduct of research and to the protection at all times of the interests, comfort, and safety of study participants. The information provided in this form is being given to you so that you may understand the procedures, risks and benefits associated with this research.

This consent form is only part of the process of informed consent. It should tell you what the research is about and what your participation will involve. If you would like more details, feel free to ask the researcher presenting this form at any time. Please take the time to read this carefully and to understand any accompanying information.

Purpose of the study:

Explain in simple lay terms the exact purpose of the research study. It may also be appropriate to provide an explanation of why they have been asked to participate.

Study Procedures:

Explain in simple lay terms exactly what will happen to them if they participate in the study.

If applicable include the following:

- If the study involves a control group, describe terms such as randomization, (How it will be done – i.e. flip of a coin?),
- Describe how many sessions or visits, amount of time required for each visit, amount of time required for interviews, questionnaires, etc.
- Indicate where the research will be carried out (location of participation).
- If the study takes place in the elementary or secondary schools and involves the use of class time, include a description of what students whose parents refuse participation will do during the time that the other students are involved with the study.

- If the study involves analysis of tests or activities that are a part of regular class routine, then explain that the results of those who do not participate will not be included in the research.
- If videotaping is involved, explain that those not participating will not be videotaped.

This project has been reviewed and granted a certificate of approval by the OC Research Ethics Board.

Potential risks and benefits:

Describe any possible discomforts and/or inconveniences associated with study participation and known or suspected short and long-term risks and benefits, and factors which might lead to refusal to participate.

Confidentiality:

Include a statement that assures that the participant's identity will be kept strictly confidential and describe how this will be accomplished (e.g. all documents will be identified only by code number and kept in a locked filing cabinet; participants will not be identified by name in any reports of the completed study). If the data records are kept on a computer hard disk, describe how the security of the computer record will be maintained. Note: Do not say that the information will be kept confidential, since it will be published.

Remuneration/Compensation:

In order to defray the costs of *inconvenience/transportation/loss of wages* each participant will be *reimbursed or will receive an honorarium* in the amount of \$#. If course credit is available to students, explain the process. Remuneration or compensation should not be dependent on completion of the project, but should be pro-rated for those that withdraw before completion.

Contact for information about the study:

If you have any questions or desire further information with respect to this study, you may contact [Principal Investigator] or one of [his/her] associates at [telephone number].

If any new information becomes available during the course of the study that may affect your willingness to continue participating, you will be advised by [Principal Investigator] or one of [his/her] associates at [telephone number].

Copies of the results of this study, upon its completion, may be obtained by _____ .

Contact for concerns about the rights of research participants:

If you have any concerns about your treatment or rights as a research participant, you may contact the Chair, Research Ethics Board through the Office of Research Services at reb@okanagan.bc.ca.

Consent:

Your participation in this study is entirely voluntary and you may refuse to participate or withdraw your participation at any time without consequence. Your signature on this form indicates that you understand the information provided regarding this research project including all procedures and the personal risks involved. Your participation in this project is in no way related to your employment contract or to your status as a patient, client or student (where applicable). (*Investigators – please choose one*). You understand that your identity and any identifying information obtained will be kept confidential.

Your signature below indicates that you consent to participate in this study. You will receive a copy of this consent form for your own records.

Name of study participant (Please Print): _____

Participant's signature _____ Date _____

Investigator and/or Delegate's signature _____ Date _____

On parental consent forms, include a statement of choice, for example:
"I consent/I do not consent (circle one) to my child's participation in this study."

Please note that parents must be provided with a copy of the parental consent form. It is acceptable to include a separate section for signatures so that they may return the signature page or section and keep the information contained in the consent form for their personal records.

Printed name of Study Participant _____

Printed Name of Participant's Parent or Guardian _____

Relationship to Study Participant _____

Signature of Parent or Guardian _____ Date _____

Investigator and/or Delegate's signature: _____ Date _____