Guidance Note
Appendix 2

SAMPLE CONSENT FORM

Notes:

• Type size - no smaller than the type on this page (Century Gothic - 12)

• 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 Tools/Options/Spelling& Grammar and by checking Show readability statistics.

• Write out all acronyms the first time they appear on each page

• Number the pages i.e. 1 of 3, 2 of 3, 3 of 3 etc.

• Include a version date in a footnote at the bottom of each page of the consent form.

• All information required by the subject 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 subject), including letterhead.

• Spelling and grammar must be corrected before it is submitted for review. This includes the correct spelling of ‘Principal’ (Investigator).

• The consent form should be written in the second person. Use ‘you’ not ‘I’.

• Please highlight any changes to the consent form, whether originating with the investigators or sponsor or requested by the Research Ethics Board.

• Any changes to the application or consent form must be approved by the Research Ethics Board before the research begins or continues.

This 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; however please feel free to contact any member of the Board or Shirley Thompson, Manager, Behavioural Research Ethics Board (604) 827-5112 for advice or assistance.
Identify this document as a “Consent Form”  
[Title of Study]

If the study involves more than one consent or assent form, in addition to the title indicate to whom it is directed (i.e. parent, child, teacher, focus group participant, etc.)

**Principal Investigator:** Be sure that 'Principal' is not misspelled 'Principle'. Include the Principal Investigator’s Name, UBC Dept, and contact telephone number. Also, note that the Principal Investigator must have a UBC Faculty appointment (for exceptions refer to guidance note #1.1).

Graduate students must include the name and telephone number of their Faculty Advisor as the Principal Investigator.

**Co-Investigator(s):** Name, UBC Department, Institution, and contact telephone number. UBC students should identify themselves as such and include the degree and 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 subject must be informed of what use will be made of the information and who will have access.

**Sponsor:**
If the investigators have received a grant or contract to conduct this study, include the name of the industry sponsor or granting agency. Also, if applicable, include a statement of any actual or potential conflict of interest on the part of the researchers or sponsors.

**Purpose:**
Explain in simple lay terms exactly the purpose of the experiment. It may also be appropriate to provide an explanation of why they have been asked to participate. For example, “You are being invited to take part in this research study because – describe the characteristics of the sample population being recruited or the inclusion criteria”

**Study Procedures:**
Explain in simple lay terms exactly what will happen to them if they participate in the study. Describe the total amount of time required of a subject if they participate in the research.

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.
- 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 the study involves “participatory action research”, describe the research-related procedures or data collection methods; for example, how will their participation in the research project differ from the normal activities.
- If the study involves behavioural therapy, describe what alternatives or other treatment options are available to the subject outside of the research project.
- If audio-taping is involved, include a statement to that effect and describe under Confidentiality how you will ensure the confidentiality of the tapes.
- If videotaping is involved, explain that those not participating will not be videotaped.

Potential Risks:
Describe all known risks, (for example: psychological, cultural, privacy, confidentiality), and a description of the procedures in place to minimize risks or to provide counselling or referral for those in distress. See Guidance Note 6.3.

Potential Benefits:
Describe the possible benefits, if any, to the subject. If there are any anticipated benefits to society or to a specific group describe this in a separate statement.

If the investigators can provide the subject with the results of the study, describe how this will be accomplished; for example, include an option on the consent form to provide a mailing address for a report on the findings.

Confidentiality:
Include a statement that assures that the subject'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. Subjects 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.

If the study involves focus groups, the 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.”

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 University 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:
Include an offer to answer any inquiries concerning the procedures, to ensure that they are fully understood by the subject. For example, “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 the research takes place out of province, provide an e-mail address or 1-800 telephone number.

Contact for concerns about the rights of research subjects:
If you have any concerns about your treatment or rights as a research subject, you may contact the Research Subject Information Line in the UBC Office of Research Services at 604-822-8598 or if long distance e-mail to RSIL@ors.ubc.ca.

Consent:
Your participation in this study is entirely voluntary and you may refuse to participate or withdraw from the study at any time without jeopardy to your [for example, employment, class standing, access to further services from the community centre, day care, etc.].

Note to investigators familiar with the CREB template: The statement “By law, this data cannot be destroyed” only applies to medical data collected in a clinical trial that could impact the health and safety of a patient. If you include this statement you will be asked to remove it.

Your signature below indicates that you have received a copy of this consent form for your own records.

Your signature indicates that you consent to participate in this study.

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 own records.

____________________________________________________
Subject Signature
(or Parent or Guardian Signature)

_______________________________
Printed Name of the Subject or Parent or Guardian signing above

The signature of a Witness is not required for behavioural research.