# APPENDIX B

## INSTRUCTIONS FOR PREPARING LETTERS OF INFORMATION & CONSENT FORMS

The purpose of informed consent is to obtain written assurance that participants in research projects clearly understand what they are agreeing to do, that they are free to decline involvement or withdraw from the study at any time, and what steps are being taken to protect them. Investigators are required to prepare a *letter of information* describing the research project and the demands it will place on participants (items 1-8 below), with a brief consent form which participants can sign stating that they have read the letter of information.

To this end, *letters of information* must include the following:

1. A brief but clear statement of the aims and procedures of the research project, specifying what will be required of participants in language that will be comprehensible to them (i.e., avoid technical terms or jargon, describe tests or instruments rather than referring to them by name); include potential benefits to the participant or to others, and the realistic likelihood of their occurrence, and details regarding reimbursement, if any;
2. a reasonable estimate of the length of time that will be taken by procedures involving participants, including the time associated with any follow-up studies;
3. a clear description of any physical or psychological risks associated with the research and the likelihood of their occurrence, or a statement that there are no known physical or psychological risks;
4. an objective description of any discomfort or inconvenience the participant may experience;
5. an instruction that participation is voluntary and that participants are free to withdraw at any time; if appropriate, add a specification that the participants are free to withdraw without jeopardizing (a) their standing in school if they are students, (b) any contractual or other relationships with the investigator if they are clients, or (c) their future care if they are patients. When questionnaires are used in studies, participants should be informed that they are not obliged to answer any questions they find objectionable or make them feel uncomfortable;
6. a statement indicating how confidentiality will be protected including both provisions for protection of anonymity in publication and the disposition of any raw data pertaining to their involvement in the study; description of any condition in which confidentiality or anonymity cannot be guaranteed or must be breached;
7. an offer to answer any inquiries, with the name, affiliation and telephone number of the investigator or a representative who will be available at this number:
8. a contact for complaints relating to ethical misconduct (Associate Academic Dean);
9. the project title (as submitted to the Ethics committee) at the top of the first page;
10. the sponsor(s) of the research, if any;
11. possible conflict of interest or commercialization of the findings.

## Consent forms must include the following:

1. the project title (as submitted to the Ethics committee) at the top of the first page.
2. the participant's name;
3. a statement that participants have read the letter of information and have any questions answered to their satisfaction and agree to be involved in the research project (or investigation or study) described;
4. a place for the date and signature of the participant, in the case of minors there should also be a place for a parent or guardian to sign. In high risk studies, the signature of a witness is advisable.
5. a contact for complaints relating to ethical misconduct (Associate Academic Dean).

In presenting this information it is important to avoid characterizations of the research project that are in any way coercive; the language of letters of information, as well as the mode of recruitment of participants, must ensure that they have a genuine choice about their involvement. It is inappropriate, for example, to over stress the importance of the project by appeal to its potential benefits ("it will cure AIDS"), to the virtues of participation ("volunteers who choose to help us..."), or to the authority of its sponsorship ("with the full support of the Ministry of X", or, "representing the Centre for X at the University of Western Ontario..."). It goes without saying that no exculpatory language limiting the participant's legal rights or releasing the researcher from liability for negligence may be included. Finally permission must be obtained from the individuals who will actually participate in the research project and provisions must be made to ensure that no pressure is brought to bear on them by supervisors, parents, guardians, sponsors, or others who may control access to them as a subject population. In particular, unless the participants are so young or incompetent that they cannot understand what they are committing themselves to-a situation which would require special provisions for protection of the subjects-the permission of those with legal or other authority over the participant will not meet the requirement for informed consent.

If a consent form is thought to be unnecessary or inadvisable, the reason should be stated and an account given of the procedure which will be used to ensure that participants have a genuine choice to participate or not to participate.

The participant should keep the written information and copy of the consent form. The researcher must retain signed consent forms for five years.