INFORMATION ON INFORMED CONSENT

FREE AND INFORMED CONSENT

Research governed by the Tri-Council Policy Statement for “Ethical Conduct for Research Involving Humans” may only begin if the prospective participants, or those authorized to consent for the participants, have been given an opportunity to give free and informed consent to take part. Once their free and informed consent has been given, it must be maintained throughout their participation in the research. If a third party is identified during the research, and the researcher wishes to use the information obtained, the researcher may wish to notify and/or gain the consent of the third party involved. Free and informed consent encompasses a process that begins with initial contact with the research participant, and carries through to the end of their direct involvement in the project. (The requirements of informed consent do not apply to the researcher, vis-à-vis the participant, once the researcher enters the writing, or publication phase of the research.)

Oral Consent

Evidence of free and informed consent should ordinarily be obtained in writing, but oral consent may also be appropriate in some circumstances. Where written consent is culturally unacceptable, or there are other justifiable reasons for not obtaining consent in writing, the procedures used to seek free and informed oral consent should be documented. A written statement of the information communicated to the participant in the consent process, signed or not, should be left with the participant. Where oral consent is appropriate, the researcher may want to make a contemporaneous journal entry of the event and circumstances.

Basic Provisions

The following represents a list of issues researchers should consider when formulating their consent process for ethics review. While not every issue may be relevant in the context of the proposed research, the following will be used by the Research Ethics Board (RE (en-CA)>BDCNi5(tan)4(c)-5(es)-3(.)]TET be relevant iy

3. For student research, the name, affiliation, and telephone number of the student's supervisor(s);

4. A statement identifying a person not directly involved in the research, for example the Department (or Program) Chair or Chair of the REB, who may be contacted should the participant have concerns about the research;

5. A clear statement of the purpose of research;

6. A full description of the procedures to be followed in the research (e.g., what is expected of participants, what they will be asked to do, what data will be collected);

7. The period of time required for the participant to take part in the project;

8. A statement indicating that participation is voluntary, and that the participant has the right to withdraw consent to participate at any time, (and can decline to answer any question or request at any time), without prejudice to pre-existing entitlements or legal rights (if relevant), and that the participant will be given continuing opportunities to decide whether or not to continue to take part;

9. Where applicable, a statement concerning recording of a participant's involvement (audio tape, video tape, photographic records, electronic data recordings, etc.); who will have access to the records, security provisions in storage, possible use in publication, and when they will be erased or destroyed;

10. Where applicable, a clear description of any potential discomforts and/or risks associated with participation in the research, or if there are any potential consequences of non-action (particularly in research involving invasive methodologies or where there is the potential for physical or psychological harm);

11. Where applicable, a clear description of the potential benefits of the research, whether to the participant or to others;

12. Where identifiable personal information is being obtained about the participant, a statement setting out the terms of confidentiality or anonymity – what information will be kept confidential, how confidentiality will be protected (example: who will have access to the information), and when confidentiality will be breached (example: when compelled by law or for the protection of health, life, and safety);

13. A statement explaining whether the participant has the option to be informed of the results of the research. This may include an option to receive copies of interviews, final findings and/or final publications. The participant should be informed of whether he or she will be identified directly or indirectly in publications resulting from the research;

14. A statement addressing the present and future anticipated use of the research;

15. A statement that the participant shall be provided with a copy of each consent letter, information sheet, or form signed or not signed, and all other relevant written information;

16. If consent is to be obtained in writing, and if the researcher judges that it is appropriate, a statement that, in signing the form, the participant understands the provisions of the consent form, and agrees to take part. For f

26. If a research assistant is employed, the researcher should consider drafting a separate confidentiality agreement to be signed by the research assistant (the agreement could include