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 (REB) when reviewing applications for ethics approval.

It is the responsibility of the researcher to address the issues that are relevant to the research, and to explain any exclusions that are made in the **Application for Review of Research Involving Humans**. The issues below are worded using the language employed by the Tri-Council Policy. All researchers have the option to employ variations of language and tone to convey the information required by the informed consent process. The spirit behind each of the issues represented below can be successfully, and concisely conveyed to research participants by using a variety of different words (running the gamut of informal to formal). The information can be formatted as a letter, an information sheet, or a form.

The purpose of an Informed Consent Form is to help to inform the potential research participant about the research and to document the participant's informed agreement to take part. One copy should be given to the research participant, and a copy signed by the participant should be retained in the researcher's files.

An Informed Consent Form must be written in language that the potential participant can understand. It must contain at least the following information:

1. A statement that the reader is being invited to participate in the research project;

2. A statement identifying the researcher(s). This statement should indicate their affiliation with St. Thomas University, and how they may be contacted;

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 forms requiring written consent from a participant, the researcher could include lines upon which the participant can sign and date his or her signature (in some circumstances, the researcher may choose to witness the signature on the consent form if he or she feels it is appropriate to attest that the participant actually signed the form); Consent letters, information sheets, or information forms should be clearly worded. Providing headings and highlighting text may help to point out important pieces of information to the potential participant. If the participant is to provide a written signature, separating the signature portion of the form might also provide added clarity.

17. When it is anticipated that participants might experience some distress as a result of participating in the research, a statement of resources available to participants (e.g., STU/UNB counselling services ph: 453-4820 or email: counsel@unb.ca)

Additional Provisions

Researchers should provide, to prospective participants, or those authorized to consent on their behalf, full disclosure of all information relevant to free and informed consent. If relevant to the proposed research, researchers may be required to include the following information for the purpose of obtaining free and informed consent:

18. If compensation is involved, complete terms and information on any costs, payments, reimbursement for expenses, or compensation for injury;

19. If the research involves the secondary use of data (data that are not publicly available, and that were originally collected for a purpose other than that of the research) that can be linked to individual participants, the individuals to whom the data refer must be notified and be given a chance to consent to the secondary use;

20. A statement explaining the possibility of commercialisation of research findings and the presence of any actual, apparent, or potential conflict of interest on the part of researchers, their institutions, or sponsors;

21. An assurance that new information will be provided in a timely manner when that information is relevant to the participant's consent to take part;

22. Where research involves the use of focus groups, a statement informing the participant that comments generated within the group may be repeated by co-participants – that while confidentiality may be secured on the part of the researcher, there is no guarantee that co-participants will keep the information imparted confidential;

23. An explanation of the responsibilities of the participant and the circumstances under which the researcher may terminate the participant's involvement;

24. A statement identifying the individual who can explain scholarly aspects of the research;

25. In the case of randomised trials, the probability of assignment to each option;

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 specific protocol for protecting the confidentiality of the information gathered).

27. If psychological distress is a possible outcome of the research, a statement of resources available to participants (e.g. STU/UNB Counselling 453-4820 or counsel@unb.ca).

28. A statement that should the participant wish to withdraw from the project before the time of publication, he or she can request the destruction of information gathered and that researchers will endeavour to comply with this request wherever possible. (Note: If the data has been stripped of identifying information, or a participant requests destruction of data after the time of publication, the researchers will not be able to destroy the data.)

Children as Research Participants:

A parent or legal guardian must provide signed written consent for the participation of children in research. As well, assent of the child is normally required where the child is old enough to understand, and evident dissent is always an indication that the child's participation in the research should be terminated.

When teenaged participants are considered by the applicant to be competent to consent without parental involvement, the applicant must provide justification for this conclusion.

Incompetent Adults as Research Participants:

For research involving adults of limited competence, signed written consent must be provided by an authorized third party. As well, assent of the participant is normally required, and evident dissent is always an indication that participation in the research should be terminated.