University of Toronto

RESEARCH SERVICES – ETHICS REVIEW OFFICE

INFORMED CONSENT

The level of disclosure should be proportionate to the likelihood and the scale of possible harm; the remote possibility of grave injury should also be disclosed.

Information to be considered in informed consent: general

The informed consent discussion, the written informed consent form and any other written information to be provided to participants should provide relevant information. This will vary according to the project, but the following items should be considered:

1. That the individual is invited to participate in research.
2. The identity of the researcher and affiliation with the University.
3. The purpose of the research.
4. The basis for inviting the individual to take part. (Include information on any criteria under which prospective participants would be excluded from participation.)
5. Where material, the approximate number of participants involved in the study.
6. The research procedures that the participant will be involved in.
7. The participant's responsibilities.
8. The reasonably foreseeable risks, harms, or inconveniences to the participant.
9. The expected duration of the participant's participation in the research.
10. The reasonably expected benefits. When there is no direct benefit to the participant, the participant should be made aware of this.
11. Where relevant, information regarding audio or video taping.
12. Measures taken regarding safety checking of equipment.
13. The compensation and/or treatment available to the participant in the event of research-related injury.
14. The anticipated payment (including any prorations) or reimbursements, if any, to the participant for participating in the research.
15. The anticipated expenses, if any, to the individual for participating in the research.
16. That the individual's participation in the research is voluntary and that the individual may refuse to participate or may withdraw from the study, at any time, without penalty or loss of benefits to which the he/she is otherwise entitled.
17. Information regarding who will have access to the data.
18. Information regarding retention of data and schedules for destruction, including audio and video tapes.
19. The degree of confidentiality and/or anonymity that will be provided. Include information on the extent to which and the manner in which records identifying the participant will be kept confidential, including any limits on confidentiality (e.g., legal reporting requirements). If the results of the study are published,

whether the participant's identity will remain confidential. Where sensitive information is collected, the risk of subpoena should be disclosed as a risk of participation.

20. That the participant or the participant's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the participant's willingness to continue participation in the study.
21. The person(s) to contact for further information regarding the research and the rights of research participants, and (where relevant) whom to contact in the event of research-related injury.
22. The foreseeable circumstances and/or reasons under which the individual's participation in the study may be terminated by the researcher.
23. A statement indicating that the researchers intend to publish the research (e.g., in scholarly publications), or that the researchers intend to make public presentations based on the research.
24. How, if at all, participants will be informed of the results of the research.
25. A statement indicating the sources of financial support for the study.
26. Where relevant, information regarding the possibility of commercialization of research findings and the presence of any apparent, actual, or potential conflict of interest on the part of the researcher, the researcher's institution, or sponsors. This requires the inclusion of a statement indicating receipt by the researcher(s) of payments from sponsor(s).

Information to be considered in informed consent: clinical trials and other biomedical research with possible therapeutic advantage for the subject

Both the informed consent discussion and the written informed consent form and any other written information to be provided to subjects should include explanations of the following:

1. The name of the study.
2. The identity of the researcher and affiliation with the University.
3. That the trial involves research, and that the individual is being invited to participate.
4. The purpose of the trial.
5. The basis for inviting the individual to take part. (Include information on any criteria under which prospective participants would be excluded from participation.)
6. Where material, the approximate number of participants involved in the trial.
7. The trial treatment(s) and the probability of random assignment to each treatment.
8. For research that involves a placebo control, information describing (a) the use of placebo; (b) how participants will be assigned to the different treatment arms; and (c) whether there is an alternative treatment available.
9. The trial procedures to be followed, including all invasive procedures.
10. Where relevant, information regarding audio or video taping.
11. Those aspects of the trial that are experimental. Explain what part of the participation is research and what part is treatment.
12. The alternative procedure(s) or course(s) of treatment that may be available to the participant, and their important potential benefits and risks.
13. The expected duration of the subject's participation in the trial. Where treatment is involved, indicate the additional time research participation will require beyond normal treatment.
14. The participant's responsibilities.
15. The reasonably foreseeable risks, harms, or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant. Include a description of the risk and nature of reasonably predictable adverse effects of treatments.
16. The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.

17. Information on foregoing alternative procedures that might be advantageous to the subject, including routine treatment that will be withheld for the sake of the research.
18. The subject's prognosis without treatment.
19. An estimate of the likelihood of success or failure of treatment.
20. The likely consequences of non-action, particularly in research related to treatment, or where invasive methodologies are involved, or where there is a potential for physical or psychological harm.
21. The compensation and/or treatment available to the subject in the event of trial-related injury.
22. The anticipated prorated payment, if any, to the individual for participating in the trial. (Include a description of the access, if any, that will be provided to continued receipt of the trial treatment if it is shown to be effective.)
23. The anticipated expenses, if any, to the individual for participating in the trial.
24. That the individual's participation in the trial is voluntary and that the subject may refuse to participate or may withdraw from the trial, at any time, without penalty or loss of benefits to which he/she is otherwise entitled.
25. Where the trial involves therapeutic interventions, the care provided if the potential participant decides not to participate.
26. That the monitor(s), the auditor(s), the Research Ethics Review Committee, and all regulatory authority(ies) will be granted direct access to the participant's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the participant or the participant's legally acceptable representative is authorizing such access.
27. That records identifying the participant will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. Indicate the limits of confidentiality, e.g., required reporting of suspected child abuse and inability to protect information from subpoena, where relevant. (Where sensitive information is collected, the risk of subpoena should be disclosed as a risk of participation.) Indicate that if the results of the trial are published, the participant's identity will remain confidential.
28. Information regarding retention of data and schedules for destruction, including audio and video tapes.
29. That the participant or the participant's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the participant's willingness to continue participation in the trial.
30. The person(s) to contact for further information regarding the trial and the rights of trial participants, and whom to contact in the event of trial-related injury.
31. The foreseeable circumstances and/or reasons under which the individual's participation in the trial may be terminated.
32. A statement indicating that the researchers intend to publish the research (e.g., in scholarly publications), or that the researchers intend to make public presentations based on the research.
33. How, if at all, participants will be informed of the results of the research.
34. A statement indicating the sources of financial support for the study.
35. Where relevant, information regarding the possibility of commercialization of research findings and the presence of any apparent or actual or potential conflict of interest on the part of the researcher, the researcher's institution, or sponsors. This requires the inclusion of a statement indicating receipt by the researcher(s) of payments from sponsor(s).

Consent form drafting principles

1. The language used (e.g., French, Portuguese, Cantonese, etc.) should be that which the subject best understands. For review purposes, submit the form in English, and explain translation arrangements. See the campus Guidelines on the Use of Human Subjects for further information.
2. Use a simple and direct style, avoiding or explaining in lay terms scientific words and expressions (e.g.,

instead of "electroencephalograph" or "EEG," say "test to show brain waves").
3. The level of language used should be appropriate to the age and comprehension/ reading level of the subject population. This may require the drafting of more than one consent form or script.
4. Avoid the use of legalistic phrases.
5. Volumes, weights, etc. should be expressed in meaningful scales as well as scientific measurements (e.g., blood draws in numbers of teaspoonfuls or proportion of a Canadian Blood Services donation).
6. Express the form in the second person (as an invitation), and include a brief acceptance clause in the first person. This is a matter of style, but is preferable.

"Do not's"

1. It should not be stated to the subject that a University Review Committee has approved the study, since this may appear to offer a guarantee of safety. In fact, approval means only that the Committee considers the risks to fall within a scale of risks which a reasonable subject may be invited to accept, and that the risk-to-benefit (or risk-to-knowledge) ratio of the study appears favourable.
2. No clause or language should be used to excuse or appear to excuse investigators or other persons or institutions involved from liability for their negligence or other fault.

Additional General Guidance

1. The participant should receive a copy of the consent form for his or her own reference.
2. The form should have an institutional heading (e.g., letterhead or the title of the hospital, University department, etc.).
3. The text of the form should also refer to the institution under whose auspices the research is to be conducted.
4. Where a parent's or guardian's consent is necessary for a minor subject, the form should be appropriately expressed, the minor named, and the guardian's capacity given. If a minor's unwritten concurrence (assent) is to be sought, the form should reflect this fact, and a place should be given for the investigator to indicate whether it was or was not obtained. If the minor is assenting in writing, the assent form should be drafted in age-appropriate language.
5. In clinical trials, the signature of the person obtaining consent should be provided. If the subject/parent/guardian cannot read the consent, a witness not associated with the investigator should attest to the fact that the consent was read to the subject/parent/ guardian.
6. The consent form should be dated, and the provincial location should be given (for jurisdictional differences in, for instance, age of majority

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