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Requirements for Informed Consent Documents

Note to Researchers

Informed consent is an on-going process that starts with the researcher's first contact with the individual and continues until the study is complete or the participant withdraws. Any discussion of informed consent with the participant, the written informed consent form and any other written information given to participants should provide adequate information for the participant to make an informed decision about his/her participation.

There are three types of consent form templates: 1) Assent form for children under the age of 16 in Canada with the exception of Quebec, it is 18 years of age; 2) Parent/Guardian's Consent for the recruitment of children under the age of 16 in Canada with the exception of Quebec, it is 18 years of age; 3) Consent form for Adult (over the age of 16-18) and mature minors.

The child should provide his/her assent and may refuse to participate even if the parent has provided their consent. The age of consent to participate in research in the Province of Quebec is 18 years of age. Section 21 of the Quebec Civil Code should be referenced for additional information as to the involvement of children in research. The Assent form for the involvement of minors in research should be used for any individuals under the age of 18.

Consent forms should be translated where it is relevant to particular communities that you wish to recruit.

General Points:

- Information letters and consent forms must be presented on institutional / departmental letterhead.
- The level of language used should be appropriate to the age and comprehension / reading level of the participant population, generally at approximately a grade 6 - 8 reading level:
 - Avoid the use of legalistic phrases.
 - Volumes, weights, etc. should be expressed in meaningful scales as well as scientific measurements (for example, blood draws in numbers of teaspoonfuls or proportion of a Canadian Blood Services donation).

- Where a parent's or guardian's consent is necessary for a minor participant, 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.
- A child under 16 years of age should provide his/her assent and may refuse to participate even if the parent has provided their consent. The age of consent to participate in research in Quebec is 18 years of age, and the assent form for the involvement of minors in research should be used for any individuals under the age of 18.
- If blood is taken, indicate total volume (for example, teaspoons and ml equivalent) and a statement about the possibility of bruising or swelling while giving blood, or some other discomforts at the site where blood is drawn and that there may be minimal chance of infection, that these discomforts are brief and transient.
- The consent form should be dated, signed and the participant should receive a copy of the consent form for his or her own reference.

The consent process will vary according to the project, but the following items should generally be included:

Introductory Information:

- Title of Research Project
- The identity of the researcher(s)
- The Purpose of the research – Why do the study? Provide a brief description of the purpose of the study
- That the individual is invited to participate in research.
- The basis for inviting the individual to take part. (Include information on any criteria under which prospective participants would be excluded from participation.)
- 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 he/she is otherwise entitled.
- If a questionnaire is being administered, participants have a choice of not answering any questions, if they don't feel comfortable in answering.

- The purpose of the research. Be sure that the description of the purpose provided in the consent documents is consistent with the purpose as described in the protocol.
- Where material, the approximate number of participants involved in the study.

What Will The Participant Be Asked To Do?

- Describe the research procedures that the participant will be involved in.
- State the expected duration of the participant's participation in the research.
- Where relevant, provide information regarding audio or video taping.

Access to Research Information:

- Information regarding who will have access to the data.
- Information regarding retention of data (including audio and video tapes) and schedules for their disposal.
- How, if at all, participants will be informed of the results of the research.
- 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.
- A statement indicating the sources of financial support for the study (if any).
- 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.

Risks / Benefits:

- The reasonably foreseeable risks, harms, or inconveniences to the participant.
- The reasonably expected benefits. When there is no direct benefit to the participant, the participant should be made aware of this.
- If blood is taken, a statement about the possibility of bruising or swelling while giving blood, or some other discomforts at the site where blood is drawn and that there may be minimal chance of infection, that these discomforts are brief and transient.

Compensation / Expenses

- The anticipated payment (including any pro-rations) or reimbursements, if any, to the participant for participating in the research.
- The anticipated expenses, if any, to the individual for participating in the research.

Confidentiality / Publication of Results

- 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 (for example, legal reporting requirements).
- A statement indicating that the researchers intend to publish the research (for example, in scholarly publications), or that the researchers intend to make public presentations based on the research. If the results of the study are published, whether the participant's identity will remain confidential.
- In those rare instances where it will not be possible to assure complete confidentiality, the limits on this obligation should be carefully explained (for example, Focus Groups, suspected child abuse).
- For Focus Groups, the Principal Investigator should consider adding a statement of the potential harm that could exist if confidentiality is violated by someone participating in these focus groups. The researchers are required to explain the two kinds of confidentiality that may apply in this situation: 1) the researchers are capable of promising confidentiality of information but 2) can't promise that the other participants will observe each others privacy.

Contact Information:

If you have any questions about this study, please contact:

Name, area code and phone number of Investigator
Collect calls will be accepted.

If you have questions about your rights as a research participant, you may contact:

The Research Ethics Board Secretariat
Holland Cross Building, Tower B
Suite 410, Address Locator 3104A, Ottawa, Ontario, K1A 0K9
Phone: (613) 941-5199 (Collect calls will be accepted)
Fax: (613) 948-6781

Consent Form "DON'TS"

- It should not be stated to the participant that a Research Ethics Board 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 participant may be invited to accept, and that the risk-to-benefit (or risk-to-knowledge) ratio of the study appears favourable.
- 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.