



Health Canada and Public
Health Agency of Canada

Santé Canada et l'Agence
de la santé publique du Canada

Research
Ethics Board

Comité d'éthique
de la recherche

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Appendix E

Template to obtain informed consent of individuals over 18 years of age

Note to Researchers

This consent form template should be used when recruiting adults over the age of 16, 18 years in Quebec and/or for mature minors. Young people between 16-18 years of age with sufficient understanding are able to give their full consent to participate in research independently of their legally authorized representative. Children under 16 years of age are able to give their full consent providing they have been counselled and do not wish to involve their parents/guardians and they have sufficient maturity to understand the nature, purpose and likely outcome of the proposed research. In addition, participation in the research must always be in the individual's best interests

A different consent form is required for participants less than 16 years of age or 18 years of age in Quebec – please see the “Assent Template” and the “Parental Consent Template”.

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.

Informed Consent Template

Title of Research Project:

- The title name must be the same as the one provided on Page I of the application form.

Investigator(s):

- Include the name and telephone number of all investigators.

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Purpose of the Research:

This section should answer the question: “Why do the study?”

- Provide a brief description of the purpose of the study.

Description of the Research:

This section should answer the questions: “How will the study be conducted and how will the participants be involved?”

- Mention that this is an invitation to participate in this study.
- Provide a brief step-by-step description of the proposed research as it will be experienced by the research participant. Be sure to distinguish between those interventions that are part of standard therapy and those that are research.
- If participants are required to undergo specific testing as part of the research, this must be explained (for example, HIV testing).
- If the participant is receiving any therapy prior to enrollment in the study and this therapy will or may be altered or discontinued as a result of participation in the study, this must be explained.
- If randomization or sequential assignment is to be carried out, this must be explained.
- If blood will be taken, indicate total volume (for example, teaspoons and ml equivalents) 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, and that these discomforts are brief and transient.
- Indicate frequency and duration of specific testing, as well as the duration of the entire study.
- Include the following statement: “If changes are made to the study or new information becomes available, you will be informed”.
- If a questionnaire is to be completed, provide a description of the questionnaire, how long it will take to complete and that the participants have a choice of not answering any questions or withdrawing at any time.
- If the study involves taking photographs, videotaping or sound recordings, mention the need to complete a separate consent form.
- If this is a Focus Group, the Principal Investigator should put a procedure in place in which the researchers caution people about the limit on confidentiality. The limit on confidentiality should also be included in the Information package that is to be sent to the individuals.

brief and transient.

- The likely consequences of non-action should be clearly explained.
- Information on adverse events must be reported immediately to the REB and may require revisions to the consent and assent forms.

Potential Benefits:

- If participants will not benefit directly from participation in this study, the following statement should be included: “You will not benefit directly from participating in this study.”
- If participants might benefit directly from participating in this study, this should be stated and the potential benefits should be described.
- If society in general or individuals with a similar condition might benefit from the results of this study, this should be explained. This statement should be in a separate paragraph from any statement about potential benefits to the participants.

Treatment Alternative(s):

- If there is no treatment alternative (for example, no available therapy), the alternative to participation in the study is non-treatment and this should be explained.
- If there is/are a treatment alternative(s), the alternative(s) should be identified and described.
- If the research is not about a treatment alternative this section may be deleted.

Confidentiality:

- The following statement regarding confidentiality will be applicable to most studies and should be included: “Confidentiality will be respected and no information that discloses the identity of the participant will be released or published without consent unless required by law. This legal obligation includes a number of circumstances, such as suspected child abuse and infectious disease, expression of suicidal ideas where research documents are ordered to be produced by a court of law and where researchers are obliged to report to the appropriate authorities.”
- If access is required by a sponsor or a regulatory authority, the above statement should be replaced with the following: “Confidentiality will be respected and no information that discloses the identity of the participant will be published without consent unless required by law. However, records identifying the participant may be given to and inspected by Health Canada/PHAC senior officials, and the REB members, for the purpose of monitoring the study).”
- 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

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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.

Reimbursement:

- Participants or their parents may be offered money for reasonable out-of-pocket expenses; (for example, transportation costs, meals, baby-sitters). In addition, participants or their parents can be reimbursed for loss of wages (minimum wage). Under no circumstances should payment be offered for harm or discomfort.
- It should be clearly stated that if the participant withdraws from the research, there will be appropriate pro-rated reimbursement.
- A thank-you gift may be presented after completion of the study, but this should not be mentioned in the research consent form.
- If the study is a randomized trial both arms of the study should be equally reimbursed unless there is a clear direct benefit to one group of participants.

Participation:

- If there are parts of the research study in which a research participant could choose not to participate this should be clearly explained.
- The following statements must be included: "Participation in research is voluntary. If you choose to participate in this study you may withdraw at any time."
- If they do not wish to participate, they do not have to provide any reason for their decision not to participate nor will they lose the benefit of any medical care to which they are entitled or are presently receiving;
- In those rare instances where it will not be possible for participants to withdraw (for example, gene therapy), the limits on the right to withdraw should be carefully explained.
- Parents of participants should be made aware that assent may be required from their child.
- Participants must be given a copy of the consent form to keep.

Waiver of Rights:

- Investigators are prohibited from seeking or obtaining waivers of participant's legal rights.

Contact:

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:

Manager, Research Ethics Board Secretariat
 70 Colombine Driveway
 9th Floor, Room 941C
 Brooke Claxton Building, Postal Locator: 0909C
 Tunney's Pasture
 Ottawa, Ontario, K1A 0K9
 Phone number (613) 941-5199
 Fax (613) 941-9093
 Email: REB-CER@hc-sc.gc.ca
 (Collect Calls will be accepted)

Consent:

The following must be the last section on the form and must be reprinted verbatim for participants 16 years of age and older (18 years of age in Quebec) :

By signing this form, I agree that:

- The study has been explained to me. Yes No
- All my questions were answered. Yes No
- Possible harm and discomforts and possible benefits (if any) of this study have been explained to me. Yes No
- I understand that I have the right not to participate and the right to stop at any time. Yes No
- I understand that I may refuse to participate without consequence. Yes No
- I have a choice of not answering any specific questions. Yes No
- I am free now, and in the future, to ask any questions about the study. Yes No
- I understand that there may be a slight risk for me while giving blood and that there may be minimal chance of infection. These discomforts are brief and transient. Yes No
- I have been told that my personal information will be kept confidential. Yes No
- I understand that no information that would identify me will be released or printed without asking me first. Yes No

- I understand that I will receive a signed copy of this consent form. Yes No

For future research projects: (if applicable)

- I agree that my data/blood samples may be used for future testing in similar research projects. Yes No

I hereby consent to participate in this study:

Name of Participant: _____

Signature

Date