INFORMED CONSENT CHECKLIST

Please note:

- You must work with two copies of the consent form - one for you and one for the participant to keep.
- Consent forms must be written in simple, direct language and use terms that the subject understands.
- Be sure that what is described in the consent form is consistent with the ethics application.

Research Information:

- □ Institutional / departmental letterhead
- □ Title of research project
- □ Identity of the researcher(s)
- □ Brief description of the purpose of the study
- □ The description of the purpose provided in the consent documents is consistent with the purpose as described in the protocol
- □ A statement inviting the participant to take part in the research
- □ A statement of the basis for inviting the individual to take part. (Include information on any criteria under which prospective participants would be excluded from participation)
- □ A statement that participation in the research is voluntary
- □ A statement 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
- □ A statement that participants have a choice of not answering any questions, if they don't feel comfortable in answering
- □ Where applicable, the approximate number of participants involved in the study has been indicated

Readability and Legibility:

- □ The level of language used is appropriate to the age and comprehension / reading level of the participant population (generally at approximately a grade 6 - 8 reading level)
- □ The level of language for populations with reading challenges(for example, if English is a second language) is in respectful, plain language either in their own language or at lower reading levels
- □ Legalistic phrases are avoided
- □ Any technical terms are clearly explained
- □ Volumes, weights, etc. are 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)

- ☐ No clause or language are used to excuse or appear to excuse investigators or other persons or institutions involved from liability for their negligence or other fault
- ☐ A font with serifs (Times Roman, for example) at font size of 12 or greater is selected
- ☐ Substantial white space in the formatting of the document is present

What Will the Participant Be Asked to Do?

- ☐ Research procedures that the participant will be involved in are described
- ☐ Expected duration of the participant's participation in the research is stated
- ☐ If relevant, information regarding audio or video recording has been provided

Access to Research Information:

- ☐ A statement with information about who will have access to the data
- ☐ A statement regarding retention of data (including audio and video recordings) and schedules for their disposal
- ☐ A statement about how, or if, participants will be informed of the results of the research
- ☐ A statement 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 or sponsors for the study (if any)
- ☐ Where relevant, a statement about any possibility of commercialization of research findings
- ☐ Where relevant, a statement about the presence of any apparent, actual, or potential conflict of interest on the part of the researcher, the researcher's institution, or sponsors

Compensation/Expenses:

- ☐ A statement about 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

Risks/Benefits:

- ☐ A statement about the reasonably foreseeable risks, harms, or inconveniences, if any, to the participant
- ☐ A statement about 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
- ☐ It has **not** been 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

Confidentiality Publication of Results:

- □ A statement about the degree of confidentiality and/or anonymity that will be provided
- □ Information on the extent to which and the manner in which records identifying the participant will be kept confidential
- □ A statement with a careful explanation of the limits of complete confidentiality, (for example, Focus Groups, suspected child abuse, suspected danger to self or others)
- □ 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 other's privacy
- □ A statement indicating if the researchers intend to publish the research (for example, in scholarly publications), or if the researchers intend to make public presentations based on the research
- □ A statement clarifying whether the participant's identity will remain confidential if the results of the study are published

Contact Information:

- □ A statement regarding contact information as follows:

  If you have any questions about this study, please contact: Name, area code and phone number of Investigator Collect calls will be accepted

Signatures:

- □ The consent form has a space for the date of signature
- □ The consent form has a space for participant signature
- □ The participant will receive a copy of the consent form for his or her own reference

Minors/ Dependent Adult Guidelines:

- □ A dependent adult or 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
- □ Where a parent's or guardian's consent is necessary for a minor participant or a dependent participant, the form should be appropriately expressed, the minor or dependent adult named, and the guardian's capacity given.

- ☐ If the minor or dependent adult is assenting in writing, the assent form should be drafted in appropriately meaningful language

Informed Consent Document Presentation Process (described in research protocol):

- ☐ Document is read along with participant
- ☐ Questions are answered
- ☐ Document may be written in participant's own language
- ☐ Document may be interpreted in participant's own language
- ☐ Qualified Interpreters should be provided if requested by participant