CONESTOGA
Connect Life and Learning

RESEARCH ETHICS OFFICE
Research Ethics Board
299 Doon Valley Drive
Kitchener, Ontario N2G 4M4
Tel: (519) 748-5220 x 2349

Project Name:

Checklist for Review of Information Letter and Consent Form

Yes	No	
☐	☐	Name of Faculty Investigator/Faculty Supervisor and Student Investigator (where applicable).
☐	☐	Departmental affiliation and contact number for Faculty Investigator/Supervisor and Student Investigator.
☐	☐	Statement that the study involves research.
☐	☐	Purpose and/or rationale of the study.
☐	☐	Description of all procedures.
☐	☐	Description of all known and/or anticipated benefits to participants from taking part in the study. If no benefits to the participant are expected, this should be indicated.
☐	☐	Description of all known and/or anticipated risks or discomforts to participants from taking part in the study, and when applicable, to an embryo, fetus or nursing infant. If no risks are anticipated, this should be indicated.
☐	☐	Safeguards to offset/mitigate risks are detailed.
☐	☐	Details of time commitment required for participation in the project.
☐	☐	Details about any plan to re-contact participants for follow-up sessions or subsequent related project.
☐	☐	Procedures to be used to ensure confidentiality of data.
☐	☐	Procedures to be used to ensure anonymity of participants.
☐	☐	Details of remuneration of participants, including pro-rating for partial completion of study.
☐	☐	Information on length of retention of data, as well as security and disposal of data.
☐	☐	A statement indicating who or what groups will receive a copy of the report or thesis.
☐	☐	A statement that participation is voluntary.
☐	☐	A statement indicating participants may withdraw agreement to participate at anytime during the study without reprisal and details on how the participants should communicate this decision to the researcher.
☐	☐	Details on how to contact the researchers in the event of additional questions about the study.
☐	☐	A statement indicating that the project has been reviewed and received ethics clearance through the REB and those participants who have concerns or questions about their involvement in the project may contact the REB Coordinator at rebcoordinator@conestogac.on.ca.

Other considerations with regard to the Information and Consent Letter (I/C L)

Yes	No	
☐	☐	Language is clear and/or easily understood by participants; does not require revisions
☐	☐	Indication that ICL will be on letterhead/departmental stationary.
☐	☐	Version for each participant group, if applicable.
☐	☐	Full title of project or lay title of project, if applicable.
☐	☐	Identification of study type e.g. thesis, pilot study, etc.
☐	☐	Details of location of study.
☐	☐	Indication that institution/agency is co-operating with or aware of study.
☐	☐	Consistency with first and second person.
☐	☐	Possibility of publication of research mentioned. In the event of publication, any records identifying the participant will be kept confidential and will not be made publicly available unless written consent has been obtained from the participant for disclosure and/or attribution.

For studies involving questionnaires/surveys, interviews, focus groups, etc., the following items should be included in the I/C L:

Yes	No	
☐	☐	For studies involving questionnaires or interviews on sensitive topics, examples of the type of questions to be asked must be provided.
☐	☐	For studies involving questionnaires or interviews, a statement must be included which indicates participants may decline answering any questions(s) they prefer not to answer.
☐	☐	For focus groups, participants need to be advised of limitations on confidentiality guarantee
☐	☐	Information regarding (audio/video) taping including storage and disposal of the tapes.

For studies involving physiological assessments, etc., the following items should be included in the I/C L:

Yes	No	
☐	☐	Details of recommended clothing or other requirements are provided
☐	☐	Safeguards for physical safety of participants
☐	☐	Medical screening form
☐	☐	Details of anticipated circumstances/medical conditions to preclude participation
☐	☐	Any additional costs
☐	☐	Information regarding (audio/video) taping including storage and disposal of the tapes.
☐	☐	Right to review audio and/or video tapes statement
☐	☐	An explanation of medical treatments available if injury occurs, and whom to contact in the event of a research-related injury

For studies involving clinical trials, the following items should be included in the ICL:

Yes	No	
☐	☐	The trial involves research
☐	☐	The appropriate number of participants involved in the trial.
☐	☐	The alternative procedures or courses of treatment that may be available to the participation and their potential benefits and risks.
☐	☐	The monitor, auditor, members of the Human Resources Ethics Committee and regulatory authorities will be granted direct access to the participant's original records for verification of clinical trial procedures and/or data.
☐	☐	The participant (or his/her legal representative) will be informed in a timely manner of information that becomes available that may be relevant to the participant's willingness to continue participation in the trial.
☐	☐	The foreseeable circumstances and/or reasons under which the participant in the trial may be terminated by the sponsor.
☐	☐	Description of compensation and/or treatment that may be available to the participant in the event of a trial-related injury.

For studies involving minors (e.g. children and adolescents) and vulnerable populations the following items should be included in the I/C L:

Yes	No	
☐	☐	Separate parental information-permission letter and child's assent form
☐	☐	Provision for signature of parent/guardian, relationship to participant on consent form

Considerations with regard to the Consent Form

Yes	No	
☐	☐	Written declaration of consent: "I agree to participate……."
☐	☐	Freedom to withdraw without penalty
☐	☐	Ethics review and clearance statement
☐	☐	Provision for signature and full name of participant and date
☐	☐	Provision for name and dated signature witness
☐	☐	Provision for name and dated signature of participant's legally authorized representative, if required.
☐	☐	Provision of separate consent for taping or quotations

Reviewer's Signature:

Date*:*