UNIVERSITY OF WATERLOO
OFFICE OF RESEARCH ETHICS

Checklist for Evaluation of Information Letter and Consent Form

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[ ] Name of Faculty Investigator/Faculty Supervisor and Student Investigator (where applicable)

[ ] Departmental affiliation and contact number/email for Faculty Investigator/Supervisor and Student Investigator

[ ] Statement that the study involves research

[ ] Purpose and/or rationale of the study

[ ] Description of all procedures in sequential order

[ ] 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; if no risks are anticipated, this should be indicated. For clinical trials, include a statement (if applicable) which identifies any risks specific to a woman who may become pregnant, a pregnant mother, nursing infant, embryo or fetus; if risks for these participants are not known, include a statement to this effect.

[ ] Safeguards to offset/mitigate risks are detailed

[ ] Details of time commitment required for participation in the project (and each component/session)

[ ] 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 and any limits to participant confidentiality

[ ] Procedures to be used to ensure anonymity of participants

[ ] Details of financial compensation or other remuneration of participants, including pro-rating for partial completion of study. Inclusion of the finance statement. For a clinical trial include any anticipated expenses associated with participation.

[ ] 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 study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Committee and that participants who have questions for the committee about their involvement in the study may contact the Chief Ethics Officer, Office of Research Ethics, at 1-519-888-4567, ext. 36005 or ore-ceo@uwaterloo.ca.

Other Considerations with regard to the Information Consent Letter (ICL)

[ ] Language is clear and/or not too complex to be understood by participants

[ ] Indication that ICL will be on letter head/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 in writing style with first and second person

[ ] Possibility of publication of research mentioned

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

[ ] For studies on sensitive topics, examples of the type of questions to be asked must be provided

[ ] A statement must be included which indicates participants may decline answering any question(s) they prefer not to answer

[ ] For focus groups, participants need to be advised of limitations on confidentiality guarantee

[ ] Information regarding (audio/video) recording including storage and disposal of the recordings

For studies involving physiological assessments, the following items should be included in the ICL:

[ ] Details of recommended clothing to bring to study session or other items/requirements

[ ] Safeguards for physical safety of participants

[ ] Health Screening form

[ ] Details of anticipated circumstances/medical conditions to preclude participation

[ ] Any additional costs

[ ] Information regarding (audio/video) recording including storage and disposal of the recordings

[ ] Right to review audio and/or video recording statement

[ ] An explanation of medical treatments/coverage available if injury occurs, and whom to contact in the event of a study-related injury. In the case of a clinical trial, include a statement indicating whether or not the sponsor will provide any coverage for a study-related injury or medical expense

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

[ ] The research involves a clinical trial

[ ] Identify the study sponsor and qualified investigator (if applicable)

[ ] The appropriate number of participants involved in the trial and their responsibilities as research participants

[ ] A description of the groups (i.e., interventions) and the possibility of being assigned to each group. Identify which procedure(s) is experimental

[ ] The alternative procedures or courses of treatment that may be available to the participation and their potential benefits and risks

[ ] A statement indicating that the monitor, auditor, members of the Clinical Research 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

[ ] A statement indicating that by signing the consent form the participant does not waive any legal rights that they would have otherwise and that any offers of compensation in the event of injury will not limit recourse to other legal remedies

[ ] 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 under which an individual's participation in the trial may be terminated by the researchers (e.g., qualified investigator) or study sponsor

[ ] A declaration of any real or perceived conflict of interest (e.g., academic/economic interests, interpersonal relationships, etc.)

[ ] A statement which indicates if this clinical trial will be registered on clinicaltrials.gov including a link to the site

[ ] A statement which indicates that restricted data (e.g., personal health information) should be encrypted while at rest and in motion and a link to the uW policy on the IST website.

[ ] A separate consent form if researchers wish to access personal health information from a health information custodian. This should clarify the data sharing arrangements which will be put into place and clarify the specific types of data to be obtained.

[ ] A statement which indicates whether Health Canada or other regulatory approval has been received (if applicable)

For studies involving minors (e.g., children and adolescents), the following items should be included in the ICL:

[ ] Separate parental information-permission letter and child's assent form

[ ] Provision for signature of parent/guardian, relationship to participant on consent form

[ ] Where applicable, a statement indicating that in cases where researchers believe that a student/individual may need protection from harm, researchers must by law report this information to authorities.

Considerations with regard to the Consent Form

[ ] Inclusion of rights and responsibility statement

[ ] 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 signature of witness

[ ] Provision of separate consent for taping or quotations