UVic/VIHA Joint Application Consent Checklist for Research with Human Participants

The following is a modified version of consent checklist initially developed by the UVic Human Research Ethics Board. The VIHA Health Research Ethics Board (HREB) uses similar guidelines. To prepare your materials you may use this checklist in combination with the Tri-Council Policy Statement and ICH Good Clinical Practice guidelines. ***See** Joint UVic/VIHA **Guidelines for more details.***

The Consent Must Always Include:

- ☐ The VIHA contact and the UVic contact for questions regarding subjects' ethical rights (see UVic/VIHA consent template for contact information)
- ☐ The name of principal investigator and contact information for local investigator/co-investigator
- ☐ The Canadian context for all sections of the consent that refer to regulatory bodies, insurance, legislation, and confidentiality issues
- ☐ The completion of editing for spelling, punctuation and grammar

General Points:

- ☐ Use plain language whenever possible. Preferably should not exceed a Grade 8 level.
- ☐ Use language level appropriate to age/ reading level of participants
- ☐ Consistent use of pronouns
- ☐ The font is at least 12-point for readability for participants and reviewers
- ☐ The pages are numbered.
- ☐ Consent requires specific version date

Introduction:

- ☐ Identify the title of the project
- ☐ State that the person is being invited to participate in a research study
- ☐ Describe the purpose of the research and why it is important
- ☐ Provide a brief explanation of how the person was recruited (how you came to contact the person) and why person was recruited (specifically in regards to privacy & confidentiality)
- ☐ Disclose any conflicts of interest.
- ☐ Disclose if researcher is in any way in a position of authority of power over participants
- ☐ State who is sponsoring or funding the research (if applicable)
- ☐ Indicate if the project is research for a graduate thesis, dissertation or project **(**if applicable)
- ☐ Provide the name and identity of the researcher(s) and affiliation with the University (e.g., graduate student, Professor of Nursing) (if applicable)

Compensation:

- ☐ Provide information about any payment, compensation or contribution for participation, and reasons they are considered necessary (include compensation available for trial related injuries if applicable)
- ☐ Inform research participants if their physician will receive compensation for enrolling them in a study

Conditions for Participating:

- ☐ State that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled
- ☐ State that participant can withdraw from the study, at any time, without negative consequences
- ☐ For research with interviews/ questionnaires specify that subject has the right to decline answering any question and may do so without prejudice
- ☐ Provide a clear explanation of what will happen to the data of a person who withdraws (e.g., it will be returned or destroyed, only data up until time of withdrawal will be included in the analysis, it is logistically impossible to remove individual participant data).
- ☐ Describe nature of the trial (i.e. including information re: randomization, placebo, experimental aspects of trial) and subjects responsibilities (i.e. time commitment, anticipated expenses, participating with invasive procedures)
- ☐ State the approximate numbers of subjects involved in the study
- ☐ Provide a clear offer to answer any questions subject may have concerning the procedures
- ☐ State that a copy of the consent form (when written consent is obtained) will be left with the participant and a copy will be kept by the researcher

Benefits / Risks:

- ☐ Describe potential benefits to study participants as well as potential benefits to society. When there is no intended clinical benefit to the subject, the subject should be made aware of this
- ☐ Describe any possible risks (including risk to fetus) or discomforts. Include all significant adverse experiences that the study participant may encounter and probability of their occurrence when known
- ☐ State the plan for minimizing possible stressors or risks and for responding to them if they arise.
- ☐ Disclose alternative procedure(s) and/or courses of treatment available to research participants (e.g., available standard medical therapy) if applicable

Access to Information and Confidentiality/Publication of Results:

- ☐ Indicate what data will be confidential or anonymous in nature
- ☐ Specify limits on anonymity and confidentiality, if any (i.e. applicable rules or laws, disclaimer for focus groups, small number of participants such that they could be identified,)
- ☐ State who will have access to the data, including specifically who will have access to personally identifiable data. If applicable state who will have access to subject's medical records for verification of clinical trial procedures and/or data, (i.e. monitors, ethic boards, auditors, regulatory authorities)
- ☐ Explain implications for any personal identifying information leaving Canada (i.e. the Patriot Act)
- ☐ If photocopying is required consent needs to specify this as well as state what is being photocopied
- ☐ Include information regarding audio/videotaping/photographing and the option to explicitly consent to such recording – if applicable
- ☐ Specify how confidential data will be stored during the project, how long it will be stored and what will be done with it at the completion of the project.
- ☐ Specify use of data, including commercial purposes
- ☐ Make statement regarding researcher's intent to publish/ make public presentations based on the research and whether or not participant's identity will remain confidential (if applicable)
- ☐ Include statement that subjects will be informed in a timely manner of any new information found during course of the trial which may relate to the subject's willingness to continue participating
- ☐ State whether and how subjects will /will not be provided feedback on results of the study.