SECTION 3. APPENDICES

There are three appendices:
(1) Checklist for a complete application,
(2) Consent form notes and example,
(3) List of what reviewers typically look for (the list is from the SSHREB's document *Confirmation of Supervisor's Review*).

3.1 Checklist. Append all relevant material to this application. This may include:

- ☐ Recruitment Documents (posters, verbal scripts, online postings, any invitations to participate, etc.)
- ☐ Screening Documents
- ☐ Consent Forms (see section 3.2 below)
- ☐ Research Instruments (questionnaires, surveys, interview or focus group questions, etc.)
- ☐ Debriefing Forms
- ☐ Permission Letters (Aboriginal Band Council, School Board, Director of a long-term care facility)

3.2 Consent Form

Guidance on the information to be provided in the consent form is described in *Guidance for Submitting an Application for Research Ethics Review – Undergraduate Students*, available from Dalhousie's Research Ethics website <URL:http://www.dal.ca/dept/research-services/services/ethics-research-reviews/research-ethics-board-approval.html>.

A sample consent form follows and may be used in conjunction with the information in the Guidance document to help you develop your consent form. Remember to use clear, simple language (grade 8 comprehension level with neither technical jargon nor acronyms) in a readable typeface and font size.

Consent forms must have a Dalhousie logo on the first page

Consent forms must be clearly identified as such on the first page

CONSENT FORM

Project Title: ***

We invite you to take part in a research study being conducted by [all group member's names] who are students at Dalhousie University, as part of their CSCI 3160 course for their undergraduate degrees. Taking part in the research is up to you and you can leave the study at any time. There will be no impact on [your studies/your employment/your performance evaluation/the services you receive] if you decide not to participate in the research. The information below tells you about what you will be asked to do and about any benefit, risk, or discomfort that you might experience. You should discuss any questions you have about this study with [phase leader's name] or [professor's name].

Who Is Conducting the Research Study

This section should identify the names and rôles of the various people who will be involved in the research. This would include the Phase Leader and the Professor.

Purpose and Outline of the Research Study

Asterisks are used as placeholders in this example. Replace them with appropriate text for your form

This research looks at ***

[This section briefly explains the overall approach of the study in plain language, and what the researcher hopes to achieve. It should provide enough information so that the intent of the study is clear, without biasing the participation of the participant. Researchers should avoid the use of coercive language (such as stating that the success of the researcher's project relies on the participation of the participant). Terms such as 'qualitative study' 'open-ended interview' 'participant observation' should not be used unless they are explained carefully, as they may not be meaningful to participants. If there is to be deception or incomplete disclosure of the purpose of the study for any reason, participants should be told that they will be given additional information about the study after their participation is complete (i.e., a debriefing).]

Who Can Participate in the Research Study

This section should explain what characteristics the participant must have to be eligible for participation in the study, including any relevant personal history. The language used should be simple and direct... 'You may participate in this study if you are...'. Any conditions (e.g., being above or below a certain age) that exclude a participant from participation must also be listed here. If any screening activities are planned, these should be described.

Pages of the consent form should be numbered and labeled with the name of the project to prevent confusion.

What You Will Be Asked to Do

To help us understand [research question], we will ask you to [details about the procedure]

[The study procedures must be stated clearly and in sufficient detail that the participant can understand what will be expected of them. The location, frequency/number and length of visits, types of procedures (interviews) and the duration of the study must be included here. This description should only include the activities that the participant will *experience*. Where several groups of individuals will take part in different components of the research, separate consent forms should be developed for each group to keep the description simple and specific.]

Possible Benefits, Risks and Discomforts

Describe any potential benefits that the participants may derive from their participation in the study. Where there are no anticipated direct personal benefits to participants, this should be explicitly stated. More altruistic benefits (e.g., contribution to knowledge) should be realistically assessed (i.e., not overstated); the text should not imply that these benefits are guaranteed. E.g., 'Participating in the study might not benefit you, but we might learn things that will benefit others.'

Risks: This should include all possible adverse events or side effects, along with the estimated probability of occurrence (if known) of any of the tasks or activities that participants will be involved in. This refers both to discomfort associated with physical procedures as well as the possibility of emotional or psychological distress caused by interviews or survey contributions. Where there is a possibility of economic repercussions, damage to relationships, or loss of privacy, these should be described. The steps that will be taken by the researcher to minimize these risks should be stated. In some instances, risks may exist for communities associated with the study (stigmatization, community discord). These should also be discussed.

Researchers should not categorically state that there is 'no risk' associated with a study. That would suggest a guarantee that is not possible given the inherent uncertainty involved in research. Where the harms or discomforts are no greater than those that are related to common experiences of everyday life, they may be described as 'minimal'. E.g., 'The risks associated with this study are minimal, and there are no known risks for participating in this research beyond being bored or fatigued. However, you will be offered breaks between activities to reduce these risks.'

Compensation / Reimbursement

If participants are to be compensated for their participation, the full extent of this compensation, and how it will be provided should be described. If participants are to be reimbursed for expenses incurred in relation to their participation (e.g., parking, transportation costs) this should be stated. Upper limits of reimbursement available (per person) should be stated also, so as not to create inappropriate expectations on the part of research participants. If participants are not being compensated this should be stated.

To thank you for your time [To reimburse you for your expenses], we will give you ….

Privacy and Confidentiality

Information that you provide to us will be kept private. Only the research team at Dalhousie University will have access to this information. We will describe and share our findings in [state where, e.g. thesis, class presentations, public media]. We will be very careful to only talk about group results so that no one will be identified. This means that ***you will not be identified in any way in our reports***. The people who work with your information have special training and have an obligation to keep all research information private. Also, we will use a participant number (not your name) in our written and computerized records so that the information we have about you contains no names. All your identifying information will be kept in a separate file, in a locked cabinet, in a locked room. All electronic records will be kept secure in a password-protected, encrypted file on the researcher's personal computer [or on a Dalhousie University secure server].

Confidentiality: Research participants should be informed how the data that they will be providing will be treated (e.g., aggregated, coded) and stored (e.g., locked file cabinet, password protected on a computer), and who will have access to it. This should be described clearly and in terms that are easily understood. In addition, the limitations of these safeguards should be stated clearly. Where there are limits to confidentiality that are imposed on researchers due to their legal obligations (i.e., duty to disclose suspected child abuse or neglect, or the abuse or neglect of an adult in need of protection) this must be stated. A simple description of what the researcher will do in such a situation should be provided. This is advisable for research that may, inadvertently, cause such disclosures to be made, and it is imperative for research that specifically deals with issues of sexual or child abuse, domestic violence or elder abuse.

Anonymity: Researchers should indicate the way in which the anonymity of participants will be achieved. Where it is not possible to protect a participant's anonymity (e.g., where they are part of a focus group) this limitation should be described. Participants should be told that they will not be identified in any reports or publications.

If You Decide to Stop Participating

You are free to leave the study at any time. If you decide to stop participating at any point in the study, you can also decide whether you want any of the information that you have contributed up to that point to be removed or if you will allow us to use that information. You can also decide for up to * months/years if you want us to remove your data. After that time, it will become impossible for us to remove it because it will already be [published/analysed/anonymised].

How to Obtain Results

We will provide you with a short description of group results when the study is finished. No individual results will be provided. You can obtain these results by [including your contact information at the end of the signature page/visiting [website address] in approximately * months/other location].

Questions

Participants must be provided with a means of having their questions about the study addressed. Ideally, a local telephone contact and electronic mail address should be available. In addition, participants should be assured that they will be provided with any new information which might affect their decision to participate in the study. For example,

We are happy to talk with you about any questions or concerns you may have about your participation in this research study. Please contact [Phase Leader's Name] (at 902 494-****, student.name@dal.ca) or [Professor's Name] (at 902 494-****, professor's address@dal.ca) at any time with questions, comments, or concerns about the research study (if you are calling long distance, please call collect). We will also tell you if any new information comes up that could affect your decision to participate.

If you have any ethical concerns about your participation in this research, you may also contact Catherine Connors, Director, Research Ethics, Dalhousie University at (902) 494-1462, or by e-mail at <ethics@dal.ca>.

The signature page must be separate from the rest of the consent form.

The project title must be clearly displayed on the signature page

Signature Page

Project Title: ***

This page should be formatted as a separate page and the title of the study must appear at the top. The signature page should be signed and dated by the research participant or by the person authorized to sign on behalf of the research participant (e.g., a parent or care giver). In the latter instance, the participant's name must also be clearly indicated.

The following statement can be used: 'I have read the explanation about this study. I have been given the opportunity to discuss it and my questions have been answered to my satisfaction. I agree to take part in this study. However I realize that my participation is voluntary and that I am free to withdraw from the study at any time.' It should be clear from the format of the page that 'I' refers to the research participant.

Explicit consent should be sought from participants for the following, where applicable:

- Audio recording or video recording
- Permission to re-contact the participant for future phases of research or other studies
- Use of substantial direct quotations
- Waiver of confidentiality

E.g. I agree that the researcher may audio-record the interview with me Yes☐ No ☐

Consent for each of these should be indicated with a separate signature line or tick box. It should be clear in the protocol why each of these permissions is being sought. If agreement to any of these is a condition of participation they should be included as a screening criterion rather than as an optional element on the signature page.

A name and date line should also be provided for the person who is obtaining consent (usually, but not always the researcher). These should be completed at the time when the consent form is signed by the participant.

With respect to permission for the use of quotations, the best practice is to confirm explicit permission for this after the interview or focus group is completed so that individuals will have a clearer understanding of what might be contained in quotations. This can be documented by having a second signature line to this effect that can be reviewed and signed *after* the data collection.

The signature page must be separate from the rest of the consent form.

The project title must be clearly displayed on the signature page.

3.3 List of questions

A list of the questions which the reviewers address when reviewing an ethics submission (quoted from Dalhousie Research Ethics form entitled *Confirmation of Supervisor's Review*, with minor changes).

Research Protocol

- Are the objectives of the study clearly described?
- Is the rationale for the study clearly outlined (e.g. reference to similar studies)?
- Is the study design appropriate to the objectives?
- Are the source and number of participants clearly stated?
- Are the eligibility criteria (screening, inclusion, exclusion) clearly defined?
- Are the methods/procedures to achieve the intended results clearly described?
- Are the methods/procedures appropriate to achieve the intended results?
- Is the rationale for the sample size clearly stated?
- Is the method of analysis described (including statistical measures for quantitative studies)?
- Does the proposed data analysis address the study's primary objective?
- Is it reasonable to do the proposed research on humans at this time?
- Is the group of research participants appropriate?
- Is the procedure for obtaining informed consent appropriate?
- Is the access to participants and methods of recruitment appropriate?
- Is deception involved and, is so, is it justified and are there appropriate arrangements for debriefing of participants?
- Has the researcher identified the risks for participants associated with their participation in the research, and has (s)he described how these will be mitigated or addressed?
- Has the researcher identified the benefits (direct and/or indirect) that may be derived from the research?

Consent Form

- Is the consent form appropriately headed (i.e. letterhead, title on front and on signature page)?
- Is the consent form simply written (Gr. 8 comprehension level, no technical jargon)?
- Does the information on the consent form match the protocol?
- Is there an introduction explaining that this is a research study, and that participation is voluntary?
- Is the purpose of the study clearly described?
- Is the study design clearly described?
- Are the conditions of the participants involvement described (inclusion/exclusion criteria)?
- Are the procedures or tasks that the participants will be asked to carryout described?
- Is the time that participation will involve described?
- Are the foreseeable risks and benefits described? Are the means to mitigate the risks described?
- If the participants are to be compensated, are the conditions and amount of compensation described?
- Is there a statement regarding the confidentiality of participant data (i.e. storage of data, access, method of publication?)
- Is there a statement regarding how the anonymity of the participant will be safeguarded?
- Are there special considerations (e.g. mental incompetence, vulnerable population)?
- Is there information about whom the participant may contact regarding the study?
- Are the appropriate signatures requested, in an acceptable format?
- Has the Research Ethics been cited should participants wish to raise concerns?