

ANNOTATED GUIDELINES FOR COMPLETING THE JOINT UVIC/VIHA APPLICATION FOR ETHICS APPROVAL FOR HUMAN PARTICIPANT RESEARCH

INTRODUCTION TO THE ANNOTATED GUIDELINES

These Guidelines will help you complete the *Joint UVic/VIHA Application for Ethics Approval for Human Participant Research*. The Guidelines and Application are intended to ensure that research studies to be undertaken within the auspices of the Vancouver Island Health Authority (VIHA) by University of Victoria (UVic) researchers follow procedures that are consistent with the current ethical standards of research practice outlined in the [Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans](#) (TCPS 2)¹. By carefully following these Guidelines you may reduce the likelihood that you will need to make revisions to your application before it is approved.

These Guidelines are organized by sections found in the *Joint UVic/VIHA Application for Ethics Approval* and include additional information to assist you in addressing a variety of ethics issues. You only need to refer to the information that is relevant to your particular research project.

Because the field of human research ethics is evolving and the TCPS is currently under review, the Joint UVic/VIHA Application Guidelines are a work-in-progress. The Guidelines suggest best practices in ethics as they are currently established. You may propose different approaches or provide a rationale as to why a particular practice that differs from the Guidelines is warranted. As more information becomes available, the Guidelines will be modified, so please check the UVic Office of Research Services (ORS) website regularly. The web version of the Guidelines represents the University of Victoria and Vancouver Island Health Authority's most current policies and procedures.

If you have questions about an issue that is not covered by the current Guidelines, please consult with the UVic Human Research Ethics Assistant at ethics@uvic.ca or Coordinator at hrethics@uvic.ca, or VIHA Research Ethics Assistant at 250-370-8620.

If you require approval from another organisation such as a school board or First Nation, please ensure that this is made explicit in your application in Section G.

Each heading below refers to a section or specific item (question) on the Joint UVic/VIHA Ethics Application Form.

IMPORTANT NOTE

This Joint Sub-Committee operates as a Sub-Committee of the two parent committees (UVic and VIHA review boards) with membership inclusive of members of each of these parent committees. The Joint Sub-Committee is designed to review minimal risk studies only. **For studies above minimal risk, you must complete the separate standard UVic and VIHA Application forms and submit to the individual institutions for full Board reviews.** Protocols that are minimal risk but complex may be referred to either of the parent committees for review.

¹ The Tri-Council Policy Statement on "Ethical Conduct for Research Involving Humans" (TCPS) was developed by the three major research councils of Canada (SSHRC: Social Sciences and Humanities Research Council; NSERC: National Sciences and Engineering Research Council; and CIHR: Canadian Institute of Health Research).

HOW TO COMPLETE THE JOINT UVIC/ VIHA APPLICATION FOR ETHICS APPROVAL

SECTION A: PRINCIPAL INVESTIGATOR

This information will be used by the Joint UVic/VIHA Sub-committee (Joint Sub-committee) to communicate with you, the principal investigator. If your project has more than one principal investigator, provide the name(s) and contact information for the other(s) in your answer to Section B Other Investigator(s) and Research Team.

SECTION B: PROJECT INFORMATION

Please provide your project title and keywords to categorize your research.

Proposed Start Date

The anticipated start date for your project should take into account the time it will take to complete and submit this application form and the period of four to six weeks required for ethical review. It is a violation of University of Victoria and Vancouver Island Health Authority policies to begin recruitment and data collection before receiving Joint UVic/VIHA Sub-committee ethics approval.

Include an anticipated completion date for your research project. Ethics approval may be granted for a maximum of three years, with the requirement of annual reports.

Personnel

Include all individuals and organizations involved in conducting your research. This includes co-principal investigator(s), co-investigators, students, assistants — paid or unpaid — and community organizations.

For VIHA personnel, estimate the time involvement that may be required of the staff at the Vancouver Island Health Authority as a result of this study being undertaken. Indicate how the cooperation of Vancouver Island Health Authority personnel directly involved will be obtained.

One reason for collecting this project information is that VIHA, the HREB and UVic Campus Security are sometimes contacted to verify the identities of individuals who present themselves as researchers and research employees. As well, the university is sometimes contacted by the public regarding the legitimacy of a project. Having accurate information about all individuals involved in the project is essential. If research team members are added or removed from the project, notify the ORS by sending a Request for Amendment form to indicate the name and role of the person(s).

SECTION C: AGREEMENT AND SIGNATURES

The signature of the applicant (principal investigator) indicates their agreement to abide by all of the University of Victoria and Vancouver Island Health Authority regulations, policies and procedures governing the ethical conduct of human research. Researchers are encouraged to review the Faculty manual, the ORS website, and the Tri-Council Policy Statement (TCPS) to learn more about what is required. The signature of the student's supervisor affirms that the research has undergone a process of approval either at the departmental level (undergraduates) or by the graduate supervisor. The Chair/Director's or Dean's signature indicates that adequate resources are in place within the department or faculty to conduct this research. The VIHA signature indicated that adequate research infrastructure is available for the conduct and completion of the research. Please print names clearly so that the Joint Sub-committee is able to identify the signatory.

SECTION D: BUDGET AND PROJECT FUNDING

Provide a summary of the total budget, by year, and indicate the sources and amounts of funding already obtained and/or being sought.

SECTION E: RESEARCH SUMMARY

Research Summary

Provide a brief description of the research.

Scholarly Review

Some form of scholarly review should occur for all research studies, but it is a requirement for research above the minimal risk threshold. Normally, the HREB considers peer review from granting agencies and graduate supervisory committee review as sufficient proof of scholarly review, but it reserves the right to require additional review.

While the UVic Human Research Ethics Board assumes a scientific review has been conducted by a student's committee and/or supervisor, or in the case of faculty members by a peer review, the VIHA Research and Ethical Approval Committee requires that each application be given a scientific review.

Research Location

Provide the geographic location where the research will be conducted, including specifics such as the facility and ward names.

Background and Rationale to the Study

State the research objectives and questions, and describe the importance of the study and its potential contributions. Include the conceptual or theoretical framework and a description of the practical and/or theoretical significance of the study. This context orients UVic/VIHA reviewers as they examine the research methods and how research participants' rights and interests are protected as described within your application.

Literature Review

A brief literature review (approx 500 words) including references is required as part of this application. Indicate how the proposed research will add to or provide increased knowledge regarding the area of study. If there is no literature on this specific problem, state this clearly and discuss studies that deal with similar issues if at all possible.

SECTION F: LEVEL OF RISK

The Tri-Council (SSHRC, NSERC and CIHR) adopted the principle of proportionate review based on the level of risk the research poses for participants. Studies which are judged to be above minimal risk, as defined by the TCPS, normally are reviewed by both the full UVic and VIHA Ethics Review Boards. Minimal risk studies are usually reviewed by the Chair, the Coordinator and two HREB members, or by the Chair and the Coordinator only. While minimal risk studies require less scrutiny, they must meet all of the same ethical requirements of higher risk studies.

Based on the TCPS 2 definition of minimal risk provided in item Section F of the application, explain the level of risk you judge your study to be. (For further information, see the [TCPS 2, Chapter 2, Section B](#)). In your explanation, refer to the characteristics of the participants (their social position, relevant life experiences) and the research activities in which they will be involved. Your assessment of the level of risk will assist the Joint Sub-committee in deciding which type of review process is appropriate for your application. The final decision on the level of risk is made by the Joint Sub-committee.

For studies above minimal risk, you must complete the separate standard UVic and VIHA Application forms and submit to the individual institutions for full Board reviews.

SECTION G: OTHER APPROVALS

If you are conducting research in an institution/agency/setting other than the University of Victoria, you may be required to obtain approval from the other authorities (e.g., School District, First Nation, other Health Authority) before proceeding with your research. Indicate if you will need approval and from whom. Attach draft letters to these authorities seeking their approval to carry out your research.

Item 16: Indigenous Community Approval

As noted under the recruitment guidelines, at this time, the Joint Sub-committee does not have specific policies on conducting ethical research with First Nations/Indigenous peoples. As different communities have established ethics guidelines and/or research protocols for conducting research within their communities, the Joint Sub-committee recommends that researchers consult with communities. Researchers may also wish to consult Protocols and Principles for Conducting Research in an Indigenous Context found on the website of the University of Victoria's Indigenous Governance Programs at <http://web.uvic.ca/igov/research/>.

SECTION H: RECRUITMENT

Item 21: Recruitment and Selection of Participants

In items 21(a) and 21(b), be as brief and specific as possible about the population that will be targeted in your study.

In item 21(c), the anticipated number of participants will indicate the scale of the research study; the number of participants may also be relevant to the issue of limits to confidentiality addressed in Section M of the Joint UVic/VIHA Ethics Application Form.²

² **Example: Limits to Confidentiality and Recruitment**

If in Section M of the Joint UVic/VIHA Ethics Application Form, a researcher claims that confidentiality will be protected, no concerns would be flagged if in item 21 (a) the researcher states that she will survey Chief Medical Officers in Canada and in 21 (b & c) she states that the estimated sample consists of 350 participants. That is, the relatively large sample size and the characteristics of the participants (health professionals in general across Canada) would not raise concerns of limits to confidentiality due to a small sample size and specific characteristics of the participants. However, if the researcher states in items 21(a) and 21(b) that she will interview four current CEOs of Manitoba hospitals, the Joint Sub-committee would cross-check her response to Section M to verify if she states that confidentiality cannot be guaranteed due to the small number of participants and ability to identify them due to their positions. The Joint Sub-committee would also examine how the researcher plans to handle these issues. Moreover, in the recruitment and consent materials, the Joint Sub-committee would examine if, and how, the researcher informs participants of the limits to confidentiality.

Ensure that you fully address item 21(e). Missing recruitment information or inappropriate recruitment methods are common reasons why researchers are required to submit revisions to their Ethics Application Form. Clearly describe all recruitment steps and attach relevant recruitment materials, such as recruitment scripts, posters and information letters.

When the Joint UVic/VIHA Sub-committee reviewers assess your recruitment process, they will consider the following:

- Are all recruitment steps included and adequately described?
- Does the recruitment process protect privacy? Does it conform to privacy requirements?
- When confidentiality is to be protected, does the recruitment process pose potential risks to confidentiality?
- Where permission to recruit participants is required from other institution or organization, is there a copy of a letter addressed to the organization that outlines the research and the request for permission to recruit participants?
- Is there is a power-over relationship? Does the recruitment process include safeguards to prevent or minimize power-over?

[For more information, see Appendix I:](#)

[Recruitment of Key Informants Whose Contact Information is Publicly Available](#)

[Recruitment Which Requires Permission from an Agency, Organization, or Institution Prior to Recruiting Participants Recruitment of First Nations/Indigenous Communities and Persons](#)

[Recruitment in a Dual-role and/or Power-over Relationship](#)

[Recruitment of Children Under the Age of 13](#)

[Recruitment of Youth Aged 13 to 16](#)

Item 22: Power Over

To be ethical research, participation must be voluntary. If the researcher is in a power-over relationship to potential participants, they may not feel entirely free to refuse to participate. Conversely, potential participants may also perceive positive inducements for their participation (e.g., gaining advantages or earning favour with the researcher).

Even when the research is of a non-sensitive nature, the Joint Sub-committee requires researchers to mitigate the power-over relationship with potential participants. The safeguard(s) that should be employed in a particular study depends on the design and nature of the research. These safeguards must be clearly explained in the application. Simple assurances such as “there will be no negative consequences” are not sufficient.

[For more information see Appendix II](#)

[Power Over](#)

[Safeguards](#)

SECTION I: DATA COLLECTION METHODS

Item 23: Data Collection

Provide a clear and succinct description of your research project, with sufficient detail so that the Joint Sub-committee can assess adherence to ethics requirements in the remainder of the application. Different data collection methods will raise different ethical issues.

Use the check boxes in item 23 to identify all of the data collection methods to be used. If your research involves methods with technical or specialized names, briefly explain these in plain language under “other.”

In 23(b) explain how these methods will be sequenced in the research process.

In 23(c) indicate method of analysis to be used for each hypotheses or question, and the strategies for handling missing data or loss of subjects. If applicable describe factors that might affect internal and external validity, and how researcher may control for these factors. Describe any limitations and/or biases that may influence the outcomes and indicate the ability to generalize the results.

[For more information see Appendix III
A Note About Emergent Research](#)

SECTION J: POSSIBLE INCONVENIENCES, BENEFITS, RISKS AND HARMS TO PARTICIPANTS

Item 24: Benefits

For research to be ethical there must be anticipated benefit to either the participants, society, or to the state of knowledge. Potential benefits should outweigh potential risks. Before the research is completed, any benefits are potential, so ensure that you do not overstate the potential benefits within recruitment and consent materials.

Items 25: Inconveniences

Describe any possible inconveniences to participants, such as time, absence from work or school, or child care expenses. Ensure you consider all the research activities/procedures. Also think about the characteristics of the participants (e.g., elderly participants, young mothers, families with a member in a palliative care hospice) and how the research may pose inconveniences for them.

Items 26 and 27: Estimate of Risk

You must assess all possible risks involved in the research, including risks to the participants,³ clearly identifiable third parties,⁴ and in some studies, to broader cultural and ethnic interests.

Participants have the right to be fully informed of any risks that may be associated with their involvement in the study. Risks are rarely, if ever, absolute; they are based on probabilities. The

³ TCPS Article 1.5(d) states: “Certain types of research, particularly in the social sciences and the humanities, may legitimately have a negative effect on public figures in politics, business, labour, the arts or other walks of life, or on organizations. Such research should not be blocked through the use of harms/benefits analysis or because of the potentially negative nature of the findings. The safeguard for those in the public arena is through public debate and discourse, and *in extremis*, through action in the court for libel.”

⁴ Third parties who have not had the opportunity to give consent should not be subjected to risk (Source: University of Windsor Research Ethics Board).

purpose of the table in item 26 is to assist you to identify all potential risks the research process may have for participants. Be sure to assess risks from the point of view of participants (e.g., think about their life circumstances and experiences). An activity that may not present a risk of harm to one individual may do so to someone with a different life history or social position.

Examples of Risks:

Psychological/emotional: Increased sadness, anxiety, fear, depression, loss of privacy and re-traumatization

Social: Loss of status, respect, alienation, changes in relationship, social stigma attached to being involved in research on issues such as substance misuse, anorexia, etc.

Physical: Pain, scarring, infection

Economic: costs of being involved in a study (child care, travel time, days off work), threats of job loss if participation becomes known.

It is unethical to conduct research with potential or known risks if measures are not taken to prevent/minimize risks and to respond appropriately should any harm occur. Participants have the right to be fully informed of potential risks. Risks identified in item 26 as “possibly” or “likely” must be described in item 27.

The Joint Sub-committee will assess whether you have adequately anticipated possible risks to participants, incorporated safeguards to prevent or minimize the potential risks, established adequate plans to respond to any harm should it occur, and appropriately informed participants about those potential risks. When reviewing your answers, the Joint Sub-committee will consider the characteristics of the participants, the nature of the research and the procedures. If relevant, in item 27(c) it is important to explain what you will do “in the moment” if a participant experiences harm.

[For more information see Appendix IV](#)

[A Word about Emotional Risks](#)

[A Word about Risks to Employment](#)

Item 28: Deception

Deception involves the use of limited or partial disclosure in the consent process. It is used when full disclosure would render the research impossible. Deception is most commonly used in social or psychological research where full disclosure could likely bias the responses received. Based on [Article 2.1C of the TCPS](#), in order for research to be ethically acceptable, the Joint Sub-committee requires that research involving deception meet five tests:

1. The research involves no more than minimal risk to the participants;
2. The deception is unlikely to adversely affect the rights and welfare of the participants;
3. The research could not practicably be carried out without deception;
4. If possible and appropriate, the participants are provided with additional pertinent information after participation; and
5. The research involves no therapeutic intervention of any kind.

If your study involves deception, please refer the TCPS 2, [TCPS 2 Article 3.7](#) and complete the [Request to Use Deception in the Conduct of Human Research](#) form available on the UVic ORS website.

SECTION K: COMPENSATION

Item 29: Compensation

Many research projects do not require compensation for participant time and contribution because they require minor amounts of participant time, do not cause significant inconvenience or they are part of student learning (e.g., for theses). However, it can be ethical to offer an honorarium or to compensate research participants for their time, inconvenience and/or contributions. If you plan to offer compensation or an honorarium to research participants, the Joint Sub-committee requires a description of the compensation/honorarium, including its monetary value or estimated monetary value and your rationale for its use. It is important to consider if the amount of the compensation is such that the participants could consider it a form of inducement. Potential participants should not be offered an honorarium that is so great that it causes them to become involved in a study in which they would otherwise choose not to participate.

If compensation is being offered, participants must be made aware that if they begin the research but then withdraw, they will still receive the compensation (or a portion thereof).⁵ This will ensure that their ongoing consent is voluntary and not induced by a belief that the compensation is available only if they complete the research activity. Ensure that this is made clear in the consent process and materials.

Example of Compensation Language for Participants who Withdraw from the Study

“If you choose to withdraw before the completion of the study, you will still be offered compensation for your participation. You will be offered an honorarium of \$20 dollars to cover your transportation costs to and from the interview and your child care expenses for that time.”

SECTION L: FREE AND INFORMED CONSENT

‘Consent is a process, not a form.’

The Joint Sub-committee strongly recommends that you read “Free and Informed Consent,” [Section 2, Article 2 of the TCPS](#). Here, the TCPS emphasizes that “Free and informed consent lies at the heart of ethical research involving human subjects” (page 2.1) and that “Rushing the process of free and informed consent or treating it as a perfunctory routine violates the principle of respect for persons, and may cause difficulty for potential subjects” (page 2.8).

Specifically, Article 2.4 states:

⁵ A person ought not to agree to participate in a study solely to receive the compensation — in fact the researcher’s aim is to provide a compensation that does not unduly “induce” a person to agree to participate. Thus, if the participant agreed to participate for reasons other than the compensation, and that person withdraws, theoretically the compensation does need to be considered as a potential “pressure” on the participant to remain in a study. However, the Joint Sub-committee requires that participants be informed that if they withdraw from a study that they will be offered the compensation (or in some circumstances, a portion thereof). This requirement is the Joint Sub-committee’s attempt to address the ethical issue of ensuring that once people engage in a study that they will not feel pressured in any way to continue.

Researchers shall provide to prospective subjects or authorized third parties, full and frank disclosure of all information relevant to free and informed consent. Throughout the free and informed consent process, the researcher must ensure that prospective subjects are given adequate opportunities to discuss and contemplate their participation.

The Joint Sub-committee closely reviews both the consent process and materials. You must use an appropriate process of consent that is meaningful to participants, and you must ensure that the granting of consent is properly documented. When developing the consent process, step out of your position as a researcher and view your study from the position of the participants. Differences of culture, age, gender, class, experiences of marginalization and so forth may give rise to important questions affecting willingness to participate, and consent cannot be validly given until these have been addressed. This is particularly true for vulnerable populations.

Item 30: Participant's Capacity to Provide Consent

According to the TCPS:

Competence refers to the ability of prospective subjects to give informed consent in accord with their own fundamental values. It involves the ability to understand the information presented, to appreciate the potential consequences of a decision, and to provide free and informed consent (page 2.9).

In item 30, you must check all boxes that describe the prospective participants and their capacity to provide free and informed consent. If you check off any box labelled "other," ensure you provide an explanation. The checkboxes in item 30 are based on the following guidelines on competency and consent adopted by the Joint Sub-committee.

For further information on competence, please refer to the [TCPS, Section 2E, Articles 2.5-2.7](#) and

[For More Information see Appendix V](#)

[Exceptions to General Guidelines for Children and Youth](#)

[Informed Consent for Children/Youth for Above Minimal Risk Studies](#)

[Competent Youth Ages 13 to 16 Years for Minimal Risk Studies](#)

[Competent Youth Ages 17 to 18 for Minimal Risk Studies](#)

[Diminished Mental Capacity](#)

[Special Vulnerable Populations](#)

Item 31: Means of Obtaining Consent

Use the checkboxes to identify which consent processes and documentation procedures will be used. Explain the consent process in item 32. The information below serves as guidelines for both items 31 and 32.

Written Consent

Written consent is the usual process for gaining and documenting informed consent. You may wish to consult [Section 2.A-D, Article 2 of the Tri-Council Policy Statement](#).

The consent process and materials are your explanation to participants of what the research entails. You are bound by all the commitments you make in the consent process, for instance in regard to the

research procedures, the means of collecting data, confidentiality protections, the use of the data, and the preservation or disposal of data.

In creating your consent materials, apart from following the checklist, the Joint Sub-committee recommends the following:

Ensure that your consent materials are consistent with the content of this application,

Consult the [Joint UVic/VIHA consent form template](#) and [checklist](#) on the [UVic ORS website](#).

Proofread your consent materials prior to submitting them.

Verbal Consent

While the TCPS' Article 2.1(b) states the preference for written evidence of free and informed consent, it acknowledges that written consent is not always appropriate, (page 2.2). If written consent will not be used, you are required to provide a rationale for why written consent is not appropriate and detail how informed consent will be documented in response to item 31. For example, some researchers will audiotape participants' verbal consent or note the circumstances and date of the consent in a research journal/log. In some situations, "witnessing" of a verbal informed consent may be employed. If verbal consent is used, the TCPS states that "in most cases a written statement of the information conveyed in the consent process, signed or not, should be left with the subject" (page 2.2).

[For more information see Appendix VI](#)

[Consent Form](#)

[Telephone Surveys/Interviews](#)

[Implied Consent](#)

[Free and Informed Consent Will Not Be Obtained](#)

Item 32: Informed Consent Process

It is recommended that researchers review the information in item 31 of the Guidelines before responding to this question. In your answer, ensure that you provide:

- A description of how you will go about obtaining consent and a rationale if you are not using written consent;
- A description of how you will document consent; and/or
- A rationale to explain why you are not seeking informed consent from your participants or from a subset of your participants (if that is the case).

Item 33: Ongoing Consent

Research may be conducted over more than one session (e.g., two interviews) or over a period of time ranging from hours to years. In such cases, provisions must be made for assuring that participants continue to consent to participate. If your research occurs over more than one session, provide an explanation of how ongoing consent will be obtained. For example, some researchers use periodic reminders or have participants initial the signed consent form on a subsequent research activity (e.g., a second interview). Other researchers develop multiple consent forms.

Item 34: Participant's Right to Withdraw

You need to make it clear to participants that they are under no obligation to participate or continue to participate in a study, and that refusal or withdrawal will have no negative consequences. You must disclose what will happen to participants' data if they withdraw from the study; if you wish to use the data collected to that point, you must seek consent to do so when the participant withdraws. If you are providing compensation to participants, see item 29 of the Guidelines for information on providing compensation to participants who withdraw. If implied consent will be used, you must inform participants that it is logistically impossible to withdraw the participants' data once the questionnaire has been returned because the data was submitted anonymously.⁶

In focus groups, it may be difficult or logistically impossible to remove the data of a person who withdraws. If the group is not too large, you may be able to do so if they can attribute the statements made by this person (on the transcript or tape). Even so, the participant's comments may still have an impact on the flow of discussion. If you are conducting focus groups, you need to consider if it is possible to remove data if someone withdraws.

If a participant withdraws and you want to use the data collected to that point, you as the researcher bear the onus to obtain consent to do so.

Example of Strategies for Obtaining Consent to Use Data When a Participant Withdraws

When a participant withdraws, some researchers take one of the following steps to seek consent to use the data collected up to the point of the participant withdrawing:

- ask participants and have them sign a release/consent form allowing the researcher to use their data;*
- ask participants and have them initial a statement on the consent form which signals consent is given to use their data;
- ask participants and record their consent to use their data in a research journal/log.

* Recommended by the Joint Sub-committee when written consent is used.

SECTION M: ANONYMITY AND CONFIDENTIALITY

Researchers may wish to review Articles [3.2, 3.3, 3.4 and 3.5 of the Tri-Council Policy Statement](#).

Below are explanations of anonymity, confidentiality, exceptions to protecting a person's identity, and privacy.⁷

Anonymity: No one, including the principal investigator, is able to associate responses or other data with the individual participants.

Confidentiality: Treatment of information that an individual has disclosed in a relationship of trust with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without explicit permission to do so. Confidentiality refers to the protection of the person's identity (anonymity) and the protection, access, control and security

⁶ If a tracking system (number codes on questionnaires) is used with the implied consent method, this would not be the case.

⁷ The explanations were adapted from the **Manual for Community Research Institutional Review Board, Michigan State University**.

of his or her data and personal information during recruitment, data collection, dissemination of data and findings and storage.

Exceptions to Protecting Identity: In certain circumstances, (e.g., oral history), it may be appropriate to use participants' names in reports or publications. In such instances, a participant's permission for the use of his or her name must be documented in the consent.

Privacy: Having control over the extent, timing, and circumstances of sharing oneself (physically, behaviourally, or intellectually) with others. The researcher ensures that the research participant determines when, how, and to what extent information about him or her is communicated to others.

Item 35: Anonymity

Anonymity means that there is no way the researcher can ever link the data to the participant. For example, anonymity is possible in circumstances such as mail-in questionnaires that have no identifying information on them.

Item 36: Confidentiality

Confidentiality in these Guidelines means the preservation of participants' anonymity, and respect for their privacy and confidentiality. The obligation to maintain confidentiality extends to the entire research team. Participants who are told that their confidentiality will be protected must be informed specifically how the researcher will protect their confidentiality. Confidentiality issues need to be considered at each phase of the research: recruitment, consent process, security, analysis, and final disposition of the data; and publication or dissemination of the data and results.⁸

Personal information and data disclosed to a researcher must be held in confidence unless the participant explicitly waives this right and is fully informed of the potential harms this might engender. Protection of a participant's identity may need to extend beyond personal identification to that of organizations, institutions, etc. In some studies, particularly in the social sciences, protecting participants' confidentiality is sometimes the key safeguard used to minimize risks.

Participants have the right to a full disclosure of how their data will be kept secure and protected. This includes where and under what conditions it will be stored, who will have access to the data and whether those with access to the data have signed a confidentiality agreement with the researcher or not (e.g., transcribers).

When confidentiality is to be protected, research data must be stored in a secure manner. This may include removing specific identifiers (e.g., contact information, combination of social factors which would make it easy to identify the participants) and using codes or pseudonyms. You should also take care to prevent data being released in a form that would permit identification of participants.

[For more information see Appendix VII
Limits to Confidentiality
Waiving Anonymity and Confidentiality](#)

SECTION N: USE AND DISPOSAL OF DATA

The Joint Sub-committee is responsible for ensuring that research studies:

⁸ National Human Research Protections Advisory Council in Recommendations on Confidentiality and Research Data Protections.

- Have appropriate provisions for the storage and disposal of data,
- Inform participants of the use(s) that will be made of their information; and
- Ensure that participants' information is not used for purposes for which the participants have not consented.

Participants have the right to full disclosure of how their data will be kept secure and protected (if appropriate/relevant). This includes where and under what conditions it will be stored, who will have access to the data and whether or not those with access to the data have signed a confidentiality agreement with the researcher (e.g., transcribers). For further information see the [TCPS, Section 3, Article 3.2](#).

Item 37: Use(s) of Data

When responding to this question please ensure that you make reference to all data forms (e.g., transcripts, audio/video-recordings, quantitative data sets, field notes).

In item 37(a) describe all the uses which the researchers and research team will have for the data. When responding to items 37(b) and 37(c), please consider the following information. Researchers may find part way through a study that the data may be useful for their other research interests or for research interests of colleagues. It is not ethical to use the information of participants for these purposes without their consent. Since this consent may not be possible to obtain after the research is completed, it is important to anticipate all possible uses prior to data collection so that appropriate consent of participants can be requested.

Item 38: Commercial Purpose

If the research may lead to commercial products, services, or other forms of commercial intellectual property, this must be disclosed to participants. The rights of participants to benefit from commercialization must be described. Related to this is the requirement to disclose any conflict of interest on the part of the researchers, their institutions or sponsors that may result from the commercialization of the intellectual property. For further information, [see the TCPS Article 2.4](#).

Item 39: Maintenance and Disposal of Data

Researchers' plans for preserving or destroying participants' data must be appropriate to the field of research and the wishes of participants. With research where the release of information could harm participants, it may be best to destroy the data collected as soon as possible.

Explain your plans for preserving and protecting participants' data or for destroying data in light of the best practices in your field of research and the wishes of participants. Some funding agencies, professional organizations and publishers have established minimum requirements for data retention (e.g., five years), after which time the data are to be destroyed. You must disclose their plans for data destruction that includes a time frame and the methods that will be employed to destroy the data (e.g., shredding, electronic file deletion). For further information, see the [TCPS, Article 3.2](#).

Item 40: Dissemination

Researchers must disclose all of the various ways they anticipate the results of the research may be disseminated (publications, presentations, film, internet, etc.). For further information, see the [TCPS, Article 2.4](#) for Table 1.

SECTION O: RESEARCHERS

Item 41: Conflict of Interest

Researchers have an obligation to disclose to participants and the Joint Sub-committee any other interests (e.g., personal, professional, economic) they or their research team members have which may conflict with the rights and interests of participants. This includes perceived and potential conflicts as well as actual conflicts. Explain any such conflicts in the research study, and how they will be managed.

Item 42: Researcher(s) Qualifications

The UVic Office of the Vice-President, Research, the Office of Research Services and VIHA Research & Academic Development Department sometimes receive calls questioning the ethical approval of the research project and the qualifications of the members of the research team. Specifically, if the study involves vulnerable or disadvantaged participants, the researchers must have the skills, awareness and sensitivity needed to engage them in an appropriate and respectful manner. Cultural differences between participants and data collectors may require that data collectors have special knowledge, skills or training.

Item 43: Risk to Researchers

The Joint Sub-committee will examine if your research project could pose risks for the data collectors. If there are potential risks, ensure that you have anticipated them, set out a plan to prevent or minimize risks and how you will respond if harm does occur.

SECTION P: FURTHER OR SPECIAL QUESTIONS

Multiple Site Research

The guide for this item is forthcoming. Please contact the UVic Ethics Coordinator at hrethics@vic.ca or 472-5202 if you have any questions.

International Research

Research performed outside the jurisdiction or country of the university must undergo prospective ethics review, where available, by a university in the country or jurisdiction where the research is done. The review body must have appropriate legal authority and apply an ethics review process with ethical and procedural safeguards comparable to the TCPS.

However, suppression of research by authoritarian regimes will not be supported and their approval will not necessarily be required. The ethics review will also take into account the safety of researchers and participants and the security of research materials. For further information see [Article 1.14 of the TCPS](#).

Other Information

If there is any additional information that you feel would aid the Joint Sub-committee in reviewing your application (e.g., relevant issues or circumstances that are not addressed in other sections), please include that information here.

Attachments

As applicable, attach the following documents to this application. Check those that are appended:

- Recruitment materials, e.g., script(s), letter(s)
- Consent form(s) (Joint UVic/VIHA [template](#) and [checklist](#) available on UVic ORS website)
- Copies of all other research instruments, including standardized instruments, questionnaires or interview guides (if large, attach sample questions)
- Approval from external organizations (or proof of having made a request for permission)
- Permission to gain access to confidential documents or materials
- [Request to Use Deception form](#) (available on ORS website)
- [Human Tissues form](#) (available on ORS website)
- Other, as needed.

Questions

If you have any questions or concerns while completing your Joint UVic/VIHA Application for Ethics Approval, please contact the Human Research Ethics Assistant at (250) 472-4545 or ethics@uvic.ca

APPENDIX I - RECRUITMENT

Recruitment of Key Informants Whose Contact Information is Publicly Available

It is appropriate for you to directly recruit government officials, business leaders, etc., using publicly available contact information such as phone numbers and email addresses from websites or business directories.

Recruitment Which Requires Permission from an Agency, Organization, or Institution Prior to Recruiting Participants

If you wish to recruit participants through an agency, organization or institution, you are normally required to first seek the agency's approval to do so. If you are required to seek such an approval, you must include this step in your recruitment process and attach a (recruitment) letter addressed to the agency, organization or institution outlining your proposed study and what you are asking them to do to assist in the recruitment process.

When reviewing the recruitment process, the Joint Sub-committee examines if the privacy of potential participants is protected in the recruitment process. For example, an agency should not directly release the client names and contact information to a researcher. To protect the privacy of potential participants, the agency, as a third party may provide a recruitment letter/recruitment advertisement to potential participants on your behalf. This material normally includes your email or phone number so that interested people can contact you, the researcher, directly. In this way, the agency will not know if the client participated or not (re: protection of privacy vis-à-vis the agency) and you will not know the identity of a client unless the client contacts you directly.

Some situations may warrant approving you to contact the potential participants directly or allowing an agency representative to ask clients' permission to release their name and contact information to you. If you propose such a recruitment strategy, in item 21(e), you are required to give a rationale for why this recruitment strategy is ethically necessary.

Recruitment of First Nations/Indigenous Communities and Persons

At this time, the Joint Sub-committee does not have a specific policy on conducting ethical research with First Nations/Indigenous peoples. As different communities have established ethics guidelines and/or research protocols for conducting research within their communities, the Joint Sub-committee recommends that you consult with the specific communities.

Recruitment in a Dual-role and/or Power-over Relationship

When reviewing recruitment procedures, the Joint Sub-committee examines if you are in a dual-role or power-over relationship to the potential participants, and if so, what recruitment safeguards have you put in place to minimize any pressure, inducement or coercion to participate in the research. The Joint Sub-committee requires that you declare your dual-role, and at a minimum, use third-party recruitment. For more information on safeguards and power-over relationships/dual-role relationships see [Appendix II of these Guidelines](#). Third party recruitment is also explained in that section.

Recruitment of Children under the Age of 13

Children under the age of 13 normally require parent authorization/consent to participate in a study. In addition to including recruitment information for parents/guardians, it is also important to provide a recruitment letter/script for children, even young children.

Depending on the nature of the study, it may be appropriate to have a single letter serve as a recruitment/consent letter for parents/guardians or, it may be more appropriate to have a separate recruitment letter followed by a letter of consent for the parents/guardians. You decide what recruitment material and process is most appropriate for the parents and the children. For children under seven years of age, researchers typically use simple verbal scripts outlining who the researcher is, what the children will be asked to do, why they are being asked to do the research activities, and what the researcher will do with the information. As well, the script needs to communicate to the children that they do not have to do the research activities if they do not want to; that they can stop whenever they want to and that is okay; and that even if their parents/guardians want them to participate, the children are the ones who decides whether or not they in fact do. Children have a veto right.

Recruitment of Youth Aged 13 to 16

Although youth aged 13 to 16 can provide their own consent in minimal risk studies, some researchers inform the parents/guardians. This can be done, for example, by sending parents/guardians an information letter. Some school districts require parental/guardian consent for students under the age of 19 when research is conducted in their schools. You must adhere to the school district's policy.

APPENDIX II – POWER OVER

Power-over

The TCPS states:

Article 2.4(e) reminds researchers of relevant ethical duties that govern potential or actual conflicts of interest, as they relate to the free and informed consent of subjects. To preserve and not abuse the trust on which many professional relations reside, researchers should separate their role as researcher from their roles as therapists, caregivers, teachers, advisors, consultants, supervisors, students or employers and the like. If a researcher is acting in dual roles, this fact must always be disclosed to the subject. Researchers should disassociate their role as researcher from other roles, in the recruitment process and throughout the project.

For a researcher who is in a dual-role (e.g., teacher and researcher), one way to “dissociate” the two roles is to exclude the pool of participants over whom the researcher has a direct power-over relationship. Or, the researcher may decide to include participants in the study only after the researcher is no longer in a power-over position. Depending on the nature of the research, this may not always be feasible, and the researcher may choose to go forward with the study with participants over whom he/she has power. In such cases, the Joint Sub-committee needs to be “convinced that a dual role is justified and that ethical problems encountered in the dual role can be overcome”⁹

⁹ Canadian Nurses Association (2002). Ethical Research Guidelines for Registered Nurses, Ottawa: Ontario

In item 22, you may respond “yes,” “no” or “varies.” The “varies” category may be used by researchers who have more than one group of participants. If you have multiple research participants, and you are in a power-over relationship with some but not others, check “varies” and provide an explanation.

If you plan to undertake research where you are in a direct power-over relationship, ensure you adequately respond to the four points in item 22. Even when the research is of a non-sensitive nature, the Joint Sub-committee requires dual-role researchers to put safeguards in place to reduce potential inducement, pressure and coercion. Simple assurances such as, there will be no negative consequences, are not accepted as substitutes for safeguards.

Safeguards

The safeguard(s) or combination of safeguards that should be employed in a particular study depends on the research design and the nature of the research. Two frequently employed strategies are (1) third-party recruitment and (2) third-party data collection.

At a minimum, third-party recruitment should be employed. The Joint Sub-committee may require more safeguards depending on the nature of the research. For some studies, in addition to third-party recruitment, third party data collection may be appropriate.

Third-party recruitment occurs when the dual-role researcher requests another person who does not have a power-over relationship to potential participants to recruit them (e.g., explain the study, provide an information letter) and (if relevant) collect signed consent forms. As well, the third-party is usually the designated person participants contact if they wish to withdraw from the study.

In some research designs, third-party recruitment completely eliminates the possibility of the researcher ever knowing who chose to participate and who did not. In other designs, a researcher may learn the identity of participants only after the researcher is no longer in a power-over relationship.

If the researcher collects his/her own data while there is still a power-over relationship, the researcher may know the identity of the participants, but third-party recruitment, at a minimum, puts a distance between the researcher and the potential participant. Depending on the nature of the study, the Joint Sub-committee may approve collecting data from participants while the researcher is still in a power-over relationship provided they use third-party recruitment.

In summary, if you are a dual-role researcher, the Joint Sub-committee requires that you:

- Explain why the dual-role research is justified and that ethical problems encountered in the dual role can be overcome. That is, you have no reasonable alternative.

Please Note: Convenience is not sufficient grounds for conducting power-over research.

- Explain the nature of the power-over relationship, how it will be explained to participants and what safeguards will be put in place to prevent inducement, pressure and coercion during participation.
- Declare this dual-role in your recruitment and informed consent materials.
- Inform participants that their decision to participate or to decline participation will not affect their access to services, grades, employment status, etc.

- Ensure that at a minimum third-party recruitment is used. Ensure that in item 22(iii) you have explained how you will prevent inducement, pressure and coercion during the recruitment stage of the research. You do not need to reproduce this information in item 21(ii), but simply make reference to it such as “Please see item 22(iii) for recruitment safeguard”.

APPENDIX III –EMERGENT RESEARCH

A Note about Emergent Research

For multi-method or other complex research (e.g., community-based research), answer this section and the following sections in ways that best explain your project.

It is important to include sufficient information about the research project so that the Joint Sub-committee can adequately assess the research ethics issues pertaining to your particular study. The Joint Sub-committee recognizes that it may be difficult to provide final, full details if you are conducting community-based research or multi-phased research where the development of subsequent phases are dependent upon the outcome of the initial phases. The Joint Sub-committee can provide ethics approval for the initial phases of a study with the understanding that more complete descriptions of the subsequent phases will be provided through amendments submitted to the Joint Sub-committee.

If you are doing multi-phased or community-based research and you cannot provide complete information in the Joint UVic/VIHA Ethics Application Form, complete all items to the best of your ability and include the information that you will be seeking subsequent amendments as your projects takes shape. For example, if you are consulting with a community-group about questions to include on a questionnaire, you cannot provide the final instrument. However, in your Joint UVic/VIHA Ethics Application Form you must describe the general direction/subject matter of the questions and state that you will submit an amendment to have the questionnaire reviewed and approved by the HREB prior to implementing it. It is recommended that you contact the Coordinator at hrethics@uvic.ca or 472-5202 for assistance and to discuss your study prior to submitting the Joint UVic/VIHA Ethics Application with the option of submitting subsequent amendments.

In item 23(d), be specific about where the research will, or may take place. If you are guaranteeing confidentiality (e.g., the participant’s identity is to remain confidential), ensure that it will not be breached by the location of your data collection.

If your research will occur over multiple sessions, indicate in item 23(e) the estimated time required for each session, as well as the total amount of time. If relevant, you may provide a range of estimated time.

APPENDIX IV - RISKS

A Word about Emotional Risks

The Joint Sub-committee frequently requires researchers to make revisions to their Ethics Application Form because they have not adequately identified emotional risk, strategies to prevent/minimize emotional risk or deal with harm should it occur. Some researchers assert that when participants have an emotional reaction or response during the research (e.g., during an interview), it does not necessarily constitute an emotional or psychological risk. While this may be true in some circumstances, the Joint Sub-committee requires that researchers whose investigations

involve sensitive, personal issues acknowledge potential emotional risks and include plans to both prevent/minimize risks and deal with harm if it does occur.

Below are examples of strategies for minimizing and responding to emotional risks in studies dealing with personal and sensitive issues. You may:

- Provide the interview questions in advance of the interview so participants are made aware of the type of questions to be discussed.
- Inform participants before starting a research activity that if they become upset, you the researcher will offer the participant a break, the chance to stop and reschedule the interview/research activity; and/or the chance to stop the interview/research activity altogether.
- If a participant becomes upset, offer to debrief with the person or offer to call someone (e.g., a participant's friend, family member) and stay with the participant until that person arrives.
- Provide a referral list of available support and/or counselling services to the participant. Some researchers attach a list to the consent letter.

If specific support resources are to be included for participants (e.g., counselling, debriefing) you must describe the types of supports, who provides them, when they are available, and if there is any cost to the participant. These arrangements should be made prior to the submission of the Joint UVic/VIHA Ethics Application Form.

A Word about Risks to Employment

Another frequent reason why researchers are required to make revisions to the Ethics Application Form is that they do not adequately address potential risks to employment. Many organizations have policies about employees participating in research about their organization (e.g., confidentiality agreements, employee oaths). If there are potential risks to participants' employment, ensure that you adequately address this risk in your Ethics Application Form.

APPENDIX V – INFORMED CONSENT

Exceptions to General Guidelines for Children and Youth

The Joint Sub-committee may approve a study that does not conform to the specific Guidelines outlined below. The nature of the study, the potential risks and benefits, protecting the youth from harm, protecting the privacy and confidentiality of the youth and balancing these with parental rights and roles would be taken into consideration.

Informed Consent for Children/Youth for Above Minimal Risk Studies

- Normally, both parental/guardian and youth (up to age 19) consent is required.
- For minimal risk studies, competent children under age 13 years give own assent and parents/guardians consent is normally required.
- Age in and of itself does not determine competency and even young children have the right to informed consent if they are capable of comprehending what is expected. A child's veto over-rides consent given by others. Even if a child is not competent to give consent, she/he must still be given the opportunity to assent (agree) to participation and this assent must be maintained throughout the study period.

Note: If at any time children give any indication that they do not want to participate in the research study, it is not ethical to include them in the research, regardless of parental or guardian consent.

As noted in the recruitment section of the Guidelines, for children under seven years of age, researchers typically use simple verbal scripts outlining who the researcher is, what the children will be asked to do, why they are being asked to do the research activities, and what the researcher will do with the information. As well, the script needs to communicate to the children that they do not have to do the research activities if they do not want to; that they can stop whenever they want to and that is okay, and that even if their parents/guardians want them to participate, the children are the ones who decide whether or not they in fact do. Children have a veto right.

Competent Youth Ages 13 to 16 Years for Minimal Risk Studies

Competent youth ages 13 to 16 years give their own consent and parental/guardian consent is not required. For some studies with this age group, it is appropriate to inform parents of the study prior to it commencing.

For example: some researchers ensure the parents are given an information letter. This allows parents to be fully informed and it provides them with an opportunity to ask the researcher questions and to discuss the study with the youth, particularly if the parents/guardians do not want them to participate in the study. Informing parents is seen as a courtesy and is respectful of parents' roles and obligations. In some situations, researchers may not want to proceed with a study unless parents are fully informed.

In other studies with 13 to 16 year olds, it may not be appropriate or not be seen as necessary to inform participants due to the nature of the study and/or the obligation to protect the privacy and confidentiality of the potential participants.

Note: For this age group, you are required to provide an explanation if you choose not to inform parents/guardians.

Competent Youth Ages 17 to 18 for Minimal Risk Studies

Competent youth ages 17 to 18 give consent and parent/guardians are not normally required to be informed. Parents/guardians may be informed of the study if there are other institutional requirements, such as a school district that requires all students to have informed consent.

Diminished Mental Capacity

Diminished mental capacity represents a continuum and each case must be judged individually and carefully. Many individuals with cognitive impairments are fully capable of providing informed consent. However, if an individual is unable to comprehend what is expected, he or she is by definition unable to give informed consent. In such cases, the individual must still provide ongoing assent to participate and a delegated guardian or authorized representative must provide consent.

Special Vulnerable Populations

Special vulnerable populations, such as inmates or hospitalized patients, are afforded special protections. Care must be taken that no coercion (threats or inducement) is used and that the consent of the appropriate authorities is also obtained. The veto of participants over-rides the consent of authorities.

APPENDIX VI – ALTERNATIVE METHODS OF GAINING CONSENT

Telephone Surveys/Interviews¹⁰

When obtaining consent for telephone surveys, include:

- A statement to the effect that the individual is being invited to participate in a research project.
- A comprehensible statement of the nature of the research project, the identity and institutional affiliation of the researcher, a description of the type of questions to be asked, and an accurate estimate of the time entailed.
- If the questions are sensitive, or there are other risks entailed by participating, these should be clearly outlined.
- A clear statement that participation is voluntary and may be withdrawn without penalty.
- A clear statement that participation is anonymous and confidential
- Note: If it is not, then the steps taken to maximize confidentiality of responses should be described.
- A brief description of how the findings will be disseminated.
- A statement to the effect that the individual may contact the researcher, the Associate Vice-President of Research at the University of Victoria or the Director of Research and Academic Development at the Vancouver Island Health Authority with questions or concerns (if the respondent desires, the contact information should be provided).

Wherever possible, a written copy of the consent protocol, complete with contact information, should be provided to respondents. Please explain how this will be handled, or why it is not feasible for your study. When a written copy is not provided, at the termination of the survey, participants should be reminded of whom they may contact with questions.

To document consent, researchers may, with the permission of the interviewee, audio-record the consent.

Implied Consent

To protect participants' anonymity in survey research when identification of the individual is not necessary for the study design (e.g., no follow-up or data-linking is necessary), the Joint Subcommittee recommends using implied consent. Implied consent is accomplished by providing participants with an information letter which contains all the relevant information normally included in a consent form, but which does not include a signature line for the participant. In this information letter, the participant is instructed that this is an anonymous survey and is asked to not put his or her name or other identifying information on the questionnaire. No signed consent form is requested because if a person mails in a survey with a consent form when their identity is not required for the study design, their signature can be linked to their data.¹¹ The implied consent process should state

¹⁰ This guide was taken from the University of Saskatchewan and slightly modified for the University of Victoria.

¹¹ Researchers who choose not to use implied consent usually employ other techniques to protect anonymity. For example, some ensure that the consent form and the questionnaire are submitted separately so at least the person's identity (the signature) cannot be linked to the actual data he/she provided.

something like: “If you return/submit this survey, it will be understood that you have consented to participate.”

Free and Informed Consent Will Not be Obtained

If you do not plan to seek free and informed consent, you must provide a rationale in item 31 which the Joint Sub-committee will examine very carefully. Before deciding to exclude the process of informed consent, please consider the information below.

Normally researchers who plan to examine personal records or files are required to obtain informed consent from the individuals and must conform to applicable privacy legislation. For example, researchers would require individuals’ consent prior to obtaining access to patients’ hospital records, students’ school records, or an agency’s client files for research purposes. If the University of Victoria researcher has access to records (e.g., a nurse who has access to patient charts, a school principal who has access to students’ records), it is unethical to access them for research purposes without first gaining informed consent. This requirement respects free and informed consent and the guiding ethical principle of protecting a person’s right to privacy and confidentiality. The Joint Sub-committee may accept researchers accessing information from such records without free and informed consent from the individuals if the information is extracted and provided to them in an anonymized format.

Informed consent is not normally required if research observations:

- Do not allow for the identification of the participants;
- Do not involve staging or manipulating the setting/circumstances; and
- Are conducted in an open setting (e.g., parking lot or public park).

However, a waiver form must be submitted to the Joint Sub-committee prior to commencing such research. If the study meets the above requirements for a waiver, but is conducted in a public space that involves observing children under the age of 13, researchers are required to put a plan in place to address potential concerns that may arise (e.g., a lone adult watching young children).

The Joint Sub-committee normally requires individual informed consent if a researcher is observing participants in a closed setting such as a hospital ward, classroom, or seniors’ facility. This is particularly important in settings where there is an expectation of confidentiality and respect for privacy. In addition, if there are secondary participants, they must at least be informed about the study. For example, for research conducted in an institutional setting such as a hospital ward, prior to observations being conducted, if patients and their families may be observed as secondary participants (e.g., they may be observed while interacting with doctors who are the primary focus/unit of analysis), then at a minimum, the patients and families must be provided information about the study and be given the opportunity to contact the researcher to ask questions or refuse to be observed. This is normally done by developing an information sheet, poster or brochure for secondary participants.

If you are conducting research on an organization, corporation or government, you are not required to seek their approval, but if you approach individuals (e.g., employees), you are required to obtain free and informed consent. According the TCPS:

Consent is not required from organizations such as corporations or governments for research about their institutions. However, individuals who are approached to participate in

a research project about their organization have the right to give free and informed consent. In particular, they should be fully informed about the views of the organization's authorities, if these are known, and of the possible consequences of participation. In this context, researchers should pay special attention to confidentiality. Private corporations and organizations have the right as institutions to refuse to cooperate with researchers or to deny them access to their private records if they so wish, and may have rules governing the conduct of their employees. However, such organizations need not be approached for consent and REBs should not require such an approach (page 2.2).

Organizational approval is required by the Joint Sub-committee when participants are being recruited through an organization. However, if the participants are not being recruited via an organization, the Joint Sub-committee does not require organizational permission. Many organizations have policies about employees participating in research about their organization (e.g., confidentiality agreements, employee oaths). If a researcher decides to research an organization without obtaining approval from the organization, in the Joint UVic/VIHA Ethics Application Form the researcher must thoroughly evaluate the risks to employees (if they are being asked to participate) and describe how these risks will be addressed in the study.

APPENDIX VII – ANONYMITY AND CONFIDENTIALITY

Limits to Confidentiality

If confidentiality cannot be assured, potential participants must be made aware of the limitations and the possible consequences in the consent process. The protection of confidentiality may be breached in a small number of situations where either the law requires it (e.g., disclosure of child abuse) or where there is a reasonable expectation of harm occurring to either the participant or others (e.g., disclosure of plans to commit suicide or murder). In cases where you are concerned about whether confidentiality should be breached, consult the Coordinator.

Possible limits to confidentiality and the requirement to breach confidentiality should be anticipated, addressed and explained to the participants. Researchers need to fully inform themselves about all laws and regulations which may affect or limit their guarantees of confidentiality. In determining potential limits to confidentiality or obligations to breach confidentiality, below is a list of questions to consider when completing item 36:

- Could the dissemination of findings compromise confidentiality?
- Is there a possibility that abuse of children or persons in care might be discovered in the course of the study?
- Is there a possibility that a participant may reveal intent to do self-harm?
- Are you conducting group interviews? The participant should be informed about limits to ensuring confidentiality of the information shared in a group interview (e.g., focus group)
- Is the use of a data/transcript release form appropriate? When the anonymity of participants is compromised (e.g., when they have provided direct words that would make them identifiable), or when culturally sensitive or personally identifying information is gathered, participants should be given the opportunity to review the final transcript and be requested to sign a transcript release form wherein they acknowledge by their signature that the transcript

accurately reflects what they said or intended to say. Participants have the right to withdraw any or all of their responses.

- Is there a possibility that your research records/data may be liable to subpoena in judicial and administrative proceedings?

Waiving Anonymity and Confidentiality

For some kinds of research (e.g., oral history) anonymity may not be necessary, possible or desirable. In such studies, research participants may not seek nor want confidentiality. The right to remain anonymous or to be identified lies with the participant. You must confirm the participants' wishes in the consent process. As the researcher, you may request participants to waive their right to confidentiality so that they can be identified within the release of findings (e.g., thesis). While participants can waive their right to confidentiality (protection of identity and their data), you need to be clear how privacy will be protected. In some studies if participants waive their right to confidentiality, it is still important to extend the protection of privacy to them. For example, for participants who will be identified in the dissemination of the research findings, it is ethically appropriate to have the participants review their interview transcripts and delete sections that they do not want to be made public through dissemination. This affords them the protection of privacy while still waiving their right to confidentiality. In other studies, for example in critical research, the researcher may not want to extend this privacy protection to the participants. Nonetheless, you are obligated to protect a participant's privacy at minimum by informing the participants that if they waive their right to confidentiality that anything they might reveal during the research may be disseminated in the research findings (e.g., the researcher needs to assure the participants are aware of this possibility). As well, you need to inform participants that they may withdraw from the study.