

Annotated Guidelines
For completing the
Human Research Ethics Board
Application for Ethics Approval for Human Participation Research

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INTRODUCTION TO THE ANNOTATED GUIDELINES

These guidelines will help you complete the Human Research Ethics Board Application for Ethics Approval for Human Participant Research. The guidelines and application are intended to ensure that research studies to be undertaken at the University of Victoria follow procedures that are consistent with the current ethical standards of research practice outlined in the [TCPS 2](#), The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.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 Human Research Ethics Board Application for Research Ethics Approval for Human Participant Research 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 always under review, the University of Victoria Human Research Ethics Board (HREB) 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 website regularly. The web version of the Guidelines represents the University of Victoria's most current document.

All forms, templates and guidelines can be found on the [Research Ethics website](#).

Quick Guides for the UVic-RAIS System are at <https://www.uvic.ca/userais/>. If you have questions about an issue that is not covered by the current Annotated Guidelines, please consult with the TCPS 2 or the Human Research Ethics Office at: ethics@uvic.ca or 250-472-4545.

If you will be conducting research that will require ethics clearance from at least one additional BC university ethics board (University of British Columbia, Simon Fraser University, University of Northern British Columbia) or BC health authority (Island Health, Fraser Health, Northern Health, Interior Health, Vancouver Coastal Health), please contact the Human Research Ethics Office at ethics@uvic.ca, or 250-472-4545.

If you also 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 or I.

Each heading below refers to a section or specific item (question) on the Research Ethics Application Form.

¹ The TCPS 2 was developed by the three major research councils of Canada: the Social Sciences and Humanities Research Council (SSHRC), the Natural Sciences and Engineering Research Council (NSERC) and the Canadian Institutes of Health Research (CIHR).

HOW TO COMPLETE THE STANDARD APPLICATION FOR ETHICS APPROVAL

SECTION A. RESEARCH TEAM

Principal Investigator/Principal Applicant

This information will be used by the Human Research Ethics Board (HREB) to communicate with you. The 'Principal Investigator (PI)' is a faculty member, adjunct professor or sessional instructor. The 'Principal Applicant' is an undergraduate student, graduate student or post-doctoral fellow who will be the lead researcher (for their thesis, dissertation, project, capstone project, honours thesis, etc.) for this study.

Faculty who supervise a student must initiate (start) the research ethics application and will then be able to grant the student access (as Principal Applicant) to the ethics application that involves that student's research. Students: your supervisor must start your research ethics application for you. The system will recognize and designate the faculty member who is your supervisor as the Principal Investigator and you as the Principal Applicant (PA). These designations are for Research Ethics compliance purposes.

If the project has more than one Principal Investigator (other than you), their names should be listed under section A.3 Research Team Members.

Also, if the project has more than one Principal Applicant, the additional individuals should be listed under section A.3 Research Team Members.

The Principal Investigator can grant access to view and/or edit the application to the research team members of their choosing, including the Principal Applicant. Once this access is granted, the research ethics application will appear on the login page of those team members and they will be able to access the RAIS application as the PI has indicated.

Research Team Members

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. The Principal Investigator can grant access to view and/or edit the application to the research team members of their choosing.

One reason for collecting this project information is that Human Research Ethics and 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 Human Research Ethics Office by contacting the Human Research Ethics Office (ethics@uvic.ca) and indicate the name and role of the person(s).

Note that a change to the principal investigator requires contacting the Human Research Ethics Office for instructions ethics@uvic.ca 250-472-4545.

SECTION B. PROJECT INFORMATION

Please enter your project title. Note that the “Project title” that you choose for this study cannot be the same as a title you or another researcher used for a different study that has been submitted by you or another researcher to the Human Research Ethics Board. All studies must have unique titles.

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. Thus anticipated start dates should be six weeks from the day of submission, at the earliest. It is a violation of University of Victoria policy to begin recruitment and data collection before receiving HREB ethics approval. You can also type ‘Upon Approval’ if you are planning to start your research as soon as ethics approval is obtained, but don’t have a set date.

Include an anticipated end date for your research project.

For the geographic location of the study, usually the name of the city, town, or region is adequate. Please provide your keywords to categorize your research.

SECTION C. PROJECT FUNDING

Information on funding sources is used to permit the release of funds and to ensure proper reporting of research ethics approval to funding agencies. For these purposes, ensure you include the exact project title used in your funding application(s), the name of the account holder and the institution holding the funds, as well as the funding status (pending, approved, etc.).

If the funding to be used for this research project is not under your name, please include the name of the research team member, who applied for/received the funding. This is the ‘Account Holder’. Make sure that you give “funding” access to this team member so the funding can be linked with the research ethics application.

SECTION D. MULTI-JURISDICTIONAL RESEARCH

This information allows the Board to understand the role of the UVic research team when the research involves team members from other jurisdictions or occurs in multiple jurisdictions.

Understanding the role of the UVic team in multi-jurisdictional research project allows the Board to assess the level of review required by the UVic HREB.

BC ETHICS HARMONIZATION INITIATIVE

Harmonization (a single coordinated review with the other institution(s) listed) may apply if you will be conducting research under the auspices of any of the institutions listed, (involving staff, patients,

health records, sites and/or recruitment through their sites, including recruitment via poster placement), as well as when members of your research team consist of faculty, staff and students from the BC institution(s) listed below. Please check with UVic HRE office if you are not sure whether your study will need to go through harmonized review.

Effective January 1, 2019, research ethics applications for all studies that involve UVic and one or more institutions listed below, must be submitted through the Provincial Research Ethics Platform ([PREP](#)), and can no longer be submitted through UVic-RAIS.

If your study involves one or more institutions listed below, please contact HRE office ethics@uvic.ca, 250-472-4321 or 250-472-4545 for more information, before proceeding with the rest of the application.

List of research ethics boards involved in BC Ethics Harmonization Initiative:

University of Northern British Columbia

University of British Columbia

Simon Fraser University

BC Cancer Agency

Children's & Women's Hospital

Providence Health Care

Island Health

Fraser Health

Interior Health

Northern Health

Vancouver Coastal Health

SECTION E. OTHER APPROVALS AND CONSULTATIONS

If you are conducting research in an institutional or agency setting other than the University of Victoria, you may be required to obtain approval from the other authorities (e.g., School District, Health Authority, Community Groups) before proceeding with your research. Indicate if you will need approval and from whom. Attach approvals you have received, correspondence that you have had, or draft letters to these authorities seeking their approval to carry out your research.

If the institutions you are conducting your research in (or involves researchers from those institutions) are part of the BC Ethics Harmonization Initiative (tooltip with list of BCEHI institutions) please see section D for more information.

If you have not yet received the approval you require, please confirm that you will forward them to the HREB once they are received. This will complete your file. Be assured that research ethics approval may be granted prior to receipt of external approvals.

Important Note: Although approval from external agencies, such as school districts, is not usually required before we grant research ethics approval, please be aware that research ethics approval is contingent upon UVic Biosafety approval.

SECTION F. 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.

SECTION G. RESEARCHER(S) QUALIFICATIONS

The Office of the Vice-President, Research and the Office of Research Services 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. When there are cultural differences between participants and data collectors, data collectors may need to have special knowledge, skills or training that allows them to respect these differences.

SECTION H. RESEARCH INVOLVING ABORIGINAL PEOPLES OF CANADA (INCLUDING FIRST NATIONS, INUIT AND MÉTIS)

“Aboriginal peoples” includes First Nations, Inuit and Métis regardless of where they reside or whether or not their names appear on an official register.

Community Engagement

Where the research is likely to affect the welfare of an Indigenous community, or communities, to which prospective participants belong, researchers shall seek engagement with the relevant community. Researchers have an obligation to become informed about, and to respect, the relevant customs and codes of research practice that apply in the particular community or communities affected by their research. The nature and extent of community engagement should be determined jointly by the researcher and the relevant community or collective, taking into account the characteristics and protocols of the community and the nature of the research. As

different communities have established ethics guidelines and/or research protocols for conducting research within their communities, the HREB recommends that researchers consult with communities as early as possible. Note that research ethics approval is not required for community consultation, as long as no participants are recruited at this stage, and no data collection takes place.

The TCPS 2 (Chapter 9) highlights the importance of community engagement and respect for community customs, protocols, codes of research practice and knowledge when conducting research with Indigenous peoples or communities. See Article 9.1 of the TCPS 2 to learn more about the conditions under which community engagement is required. Researchers may also wish to consult Protocols and Principles for Conducting Research in an Indigenous Context found on UVic's Indigenous Governance Programs website.

SECTION I. INTERNATIONAL RESEARCH

Researchers affiliated with UVic must abide by the University's policies and regulations and the requirements of the TCPS 2 when research will be conducted in whole, or in part, in another country. Where possible, researchers must also identify and satisfy the research ethics requirements of the country where the research is to be conducted. For instance, where possible and appropriate, the research must undergo prospective research ethics review, by a University, a governing body, or a relevant community group, in the country or jurisdiction where the research will be conducted. Note that approval by an international Research Ethics Board or governing body does not constitute sufficient authorization to conduct research if you have not yet obtained research ethics approval from UVic. See Chapter 8, of the TCPS 2 for further information.

Note that suppression of research by authoritarian regimes will not be supported and their approval will not necessarily be required. The research ethics review will also take into account the safety of researchers and participants and the security of research materials.

The TCPS 2 notes that Chapter 9 may be useful when undertaking research involving Indigenous peoples in other countries who endorse collective decision making as a complement to individual consent. It is critically important, however, to seek local guidance in the application or adaptation of this Policy to Indigenous peoples outside of Canada.

SECTION J. DESCRIPTION OF RESEARCH PROJECT

Purpose and Rationale of Research

In plain, non-technical language state the research objectives and questions, describe the importance of the study and its potential contributions, and provide any other background information or details that you deem relevant. Ensure there is sufficient background information and context to orient HREB reviewers as they examine the research methods and how research participants' rights and interests are protected as described within your application.

SECTION K. RECRUITMENT

Recruitment and Selection of Participants

In items K.1a, K.1b and K.1c, be as brief and specific as possible about the population that will be targeted in your study. Ensure all participant groups are identified here and throughout your application.

In item K.1d, 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 P (Anonymity and Confidentiality) of the Research Ethics Application Form.²

Ensure that you fully address items in K.2a. Missing recruitment information or inappropriate recruitment methods are common reasons why researchers are required to submit revisions to their Research Ethics Application Form. Clearly describe all recruitment steps and attach relevant recruitment materials, such as recruitment scripts, posters, information letters, etc. Ensure that recruitment information for each participant group is clearly explained.

When the 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 another 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 a power-over relationship? Does the recruitment process include safeguards to prevent or minimize power-over?
- Does the researcher have an influential relationship with the potential participants, such as family member, friend, or colleague that may lead potential participants to feel pressure to participate? Does the recruitment process include safeguards to prevent or minimize any such pressure?

For more information, see [Appendix I: Recruitment](#), which covers the following topics:

² Example: Limits to Confidentiality and Recruitment

If in Section P of the Research Ethics Application Form, a researcher claims that confidentiality will be protected, no concerns would be flagged if in item K.1a the researcher states that she will survey university professors in Canada and in item K.1d she states that the estimated sample consists of 350 participants. That is, the relatively large sample size and the characteristics of the participants (professors 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 K.1a and K.1d that she will interview four current presidents of Alberta universities from the University of Alberta, the University of Calgary, Athabasca University and the University of Lethbridge, the HREB would cross-check her response in Section Q 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 HREB would also examine how the researcher plans to handle these issues. Moreover, in the recruitment and consent materials, the HREB would examine if, and how, the researcher informs participants of the limits to confidentiality.

- Recruitment of participants whose contact information is publicly available
- Recruitment which requires permission from an agency, organization, or institution prior to recruiting participants
- Recruitment using snowball sampling methods
- Recruitment of First Nations/Indigenous communities and persons
- Recruitment in a dual-role and/or power-over relationship
- Recruitment and influential relationships (family members, friends, close colleagues, etc.)
- Recruitment of children under the age of 13
- Recruitment of youth aged 13 to 16

Sub-section: K.3: Power Relationships

For research to be conducted ethically, 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 HREB 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](#).

SECTION L. DATA COLLECTION METHODS

Sub-section: Data Collection

Provide a clear and succinct description of your research project, with sufficient detail so that the HREB 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 L.1a 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 in the appropriate places.

In L.1b explain how these methods will be sequenced in the research process.

For more information, see [Appendix III: Self-reflective and Emergent Research](#)

US Freedom Act

Data collection and storage in the United States may occur through the use of US-based online survey instruments, such as SurveyMonkey (the non-UVic hosted/owned version); through cloud

storage, or other data storage through sharing of raw data with US-based research team members, etc. When research includes data storage in the USA this data is subject to the US Freedom Act. As such, there is a possibility that information collected/stored in the US may be accessed, without the participant's knowledge or consent, by the US government in compliance with the US Freedom Act.

For this reason, the HREB requires this information to be disclosed to research participants during the consent process. (In the case of US based online surveys, this is preferably stated at the beginning of the questionnaire so that it is not overlooked by the participant.). Alternatively, you may choose to use only Canadian-based data storage and a Canadian-based survey tool.

Ensure that the location of your survey instruments and any other sources of data storage are disclosed in items L.1a and L.1b. This information should also be included in item P.2a and in item Q.3 as necessary.

SECTION M. POSSIBLE BENEFITS, INCONVIENCIES, AND RISKS OF HARM TO PARTICIPANTS

M.1: Benefits

Ethical research includes an 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.

M.2: 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.

M.3: Level of Risk

The TCPS 2 adopted the principle of proportionate review based on the level of risk the research poses for participants: the lower the level of risk, the lower the level of scrutiny (delegated review); the higher the level of risk, the higher the level of scrutiny (full Board review).

Studies which are judged to be above minimal risk, as defined by the TCPS 2, normally are reviewed by the full HREB. Minimal risk studies are usually reviewed by the Chair or Vice-Chair, the Ethics Coordinator or Facilitator, and two HREB members, or by the Chair or Vice-Chair, and the Ethics Coordinator or Facilitator only. While minimal risk studies require less scrutiny, they must meet all of the same ethical requirements as higher risk studies.

Based on the TCPS 2 definition of minimal risk provided in item M.3 of the application, explain the level of risk you judge your study to be. (For further information, see Chapter 2, of the TCPS 2). 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 HREB in deciding which type of review process is appropriate for your application. The final decision on the level of risk is made by the HREB.

M.4: Estimate of Risks of Harm

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 purpose of sub-section M.4 is to assist you in identifying 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, embarrassment, feeling demeaned

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: falls, pain, scarring, infection, physical violence

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

Incidental Findings: “Incidental findings” is a term that describes unanticipated discoveries made in the course of research but that are outside the scope of the research. Researchers should exercise caution in disclosing incidental findings that may cause needless concern to participants. When necessary, researchers should direct participants to a qualified professional to discuss the possible implications of the incidental findings for their welfare. In some cases, incidental findings may trigger legal reporting obligations (e.g., evidence of child abuse) and researchers should be aware of these obligations.⁵

It is unethical to conduct research with potential or known risks if measures are not taken to prevent or 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 M.4 as “possibly” or “likely” must be described in item M.5.

³ TCPS 2 Article 3.6, Application, states: “REBs should also be aware that some research, involving critical assessments of public, political or corporate institutions and associated public figures, for example, may be legitimately critical and/or opposed to the welfare of those individuals in a position of power, and may cause them some harm. There may be a compelling public interest in this research. Therefore, it should not be blocked through the use of risk-benefit analysis. Such research should be carried out according to the professional standards of the relevant discipline(s) or field(s) of research.”

⁴ Third parties who have not had the opportunity to give consent should not be subjected to risk

⁵ TCPS 2: Chapter 3, Article 3.4

The HREB 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 HREB will consider the characteristics of the participants, the nature of the research and the procedures. If relevant, in item M.5c it is important to explain what you will do “in the moment” if a participant experiences harm.

For more information, see [Appendix IV: Risks](#).

M.6: Risk to Researchers

The HREB 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.

M.7: 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 3.7 of the TCPS 2, in order for research to be ethically acceptable, the HREB 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 welfare of the participants;
3. The research could not practicably be carried out without deception;
4. If possible and appropriate, the participants will be debriefed and provided with additional pertinent information after participation; at which point they will have the opportunity to refuse consent; and
5. The research involves no therapeutic intervention or other clinical or diagnostic interventions

If your study involves deception, please refer to Article 3.7 of the TCPS 2 and complete the “Request to Use Deception in the Conduct of Human Research” form available on the research ethics website.

SECTION N. INCENTIVES, REIMBURSEMENT AND COMPENSATION

1: Incentives

Incentives are anything offered to participants, monetary or otherwise, for participation in research (incentives differ from reimbursements and compensation, see below for more information). Examples include gifts (homemade or store bought), gift certificates, honoraria, course credits, raffle prizes, etc. Incentives are used to encourage participation in a research project, or to honour a participant’s contribution.

If you plan to offer incentives to research participants, the HREB requires a description of the incentives, including its monetary value, or estimated monetary value, and your rationale for its use. It is important to consider if the amount of the incentive is such that the participants could

consider it a form of inducement. The onus is on the researcher to justify to the REB the use of the incentives and the level of incentives. You should take into consideration issues specific to your participants such as the economic circumstances, the age and capacity of participants, the customs and practices of the community, and the magnitude and probability of harms. Potential participants should not be offered an incentive that is so great that it causes them to become involved in a study in which they would otherwise choose not to participate.

If an incentive is being offered, participants must be made aware that if they begin the research but then withdraw, they will still receive the incentive (or a portion thereof).⁶ The TCPS 2 states that a participant should not suffer any disadvantage or reprisal for withdrawing, and that any payment due prior to the point of withdrawal, must still be provided. This means that if the research project uses a lump-sum incentive for participation, the participant that withdraws part way through data collection is entitled to the entire amount. If a payment schedule is used, participants shall be paid in proportion to their participation.⁷ This will ensure that their ongoing consent is voluntary and not induced by a belief that the incentive is available only if they complete the research activity. Ensure that this is made clear in the consent process and materials and in item N of the Research Ethics Application Form.

Example of Incentive Language for Participants who Withdraw:

“If you choose to withdraw before the completion of the study, you will still be awarded the full bonus for your participation. Full bonus points (1.5) will be awarded regardless of how much of the study tasks you have completed at the time you choose to withdraw.”

N.2 and 3: Reimbursement and 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 reimbursement for costs associated with research participation (such as transportation costs, child care expenses, etc.) or to compensate research participants for wages lost due to research participation or injury due to research participation. If you plan to offer reimbursement or compensation to research participants, the HREB requires a description of the reimbursement/compensation, including its monetary value or estimated monetary value and your rationale for its use. It is important to consider if the amount of the reimbursement/compensation is such that the participants could consider it a form of inducement.

If reimbursement/compensation is being offered, participants must be made aware that if they begin the research but then withdraw, they will still receive the reimbursement/compensation (or a portion thereof, e.g., for costs already incurred). This will ensure that everyone is aware of the

⁶ A person ought not to agree to participate in a study solely to receive an incentive — in fact the researcher’s aim is to provide an incentive that does not unduly “induce” a person to agree to participate. Thus, if the participant agreed to participate for reasons other than the incentive, and that person withdraws, theoretically the incentive does need to be considered as a potential “pressure” on the participant to remain in a study. However, the HREB requires that participants be informed that if they withdraw from a study that they will be offered the incentive (or in some circumstances, a portion thereof). This requirement is the HREB’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.

⁷ TCPS 2 Chapter 3, Article 3.1.

expectations of participation. Ensure that this is made clear in the consent process and materials and in item N.1 of the Research Ethics Application Form.

Example of Reimbursement Language for Participants who Withdraw:

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

SECTION O. FREE AND INFORMED CONSENT

‘Consent is a process not a form.’

The HREB strongly recommends that you read Section 3: The Consent Process of the TCPS 2. Here, the TCPS emphasizes that “consent encompasses a process that begins with the initial contact (e.g., recruitment) and carries through to the end of participants’ involvement in the project.”

Specifically, Article 3.2 states:

For consent to be informed, prospective participants shall be given adequate time and opportunity to assimilate the information provided, pose any questions they may have, and discuss and consider whether they will participate.

The HREB 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 O.1: Participant’s Capacity (Competence) to Provide Free and Informed Consent

According to the TCPS 2:

Capacity refers to the ability of prospective or actual participants to understand relevant information presented about a research project, and to appreciate the potential consequences of their decision to participate or not participate.

In item O.1, 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 O.1 are based on the following guidelines on competency and consent adopted by the HREB.

For further information on competence, please refer to Chapter 3, Section C of the TCPS 2 and [Appendix V: Informed Consent](#), which cover the following topics:

- Exceptions to general guidelines for children and youth
- Informed consent for children/youth for above minimal risk studies
- Competent youth ages 13-16 years for minimal risk studies
- Competent youth ages 17-18 years for minimal risk studies
- Diminished mental capacity
- Special vulnerable populations

O.2: Means of Obtaining and Documenting Consent and/or Assent:

Use the checkboxes to identify which consent processes and/or assent processes, and documentation procedures, will be used and explain the consent/assent processes in item O.3.

Written Consent

Written consent is the usual process for gaining and documenting informed consent. You may wish to consult Chapter 3 of the TCPS 2.

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 HREB recommends the following:

- Ensure that your consent materials are consistent with the content of this application
- Ensure the language and concepts used are consistent with the potential participants (e.g., if you are recruiting lay participants, avoid academic language and concepts)
- Consult the consent form template and checklist on the research ethics website
- Proofread your consent materials prior to submitting them

Verbal Consent

While the TCPS 2 Article 3.12 states that written consent in a signed statement from the participant is a common means of demonstrating consent, it acknowledges that written consent is not always appropriate. 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. For example, some researchers will audiotape participants' verbal consent or note the circumstances and date of the consent in a research journal or log. In some situations, "witnessing" of a verbal informed consent may be employed. If verbal consent is used, the TCPS 2 states that "Whether or not a consent form is signed, it may be advisable to leave a written statement of the information conveyed in the consent process with the participant".

For more information, see [Appendix VI: Alternative Methods of Gaining Consent](#).

Item O.3: Informed Consent Process

It is recommended that researchers review the information in item O.2 of the Guidelines before responding to these questions. 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).

Where processes will be distinct for different participant groups (e.g., group 1 – teachers, group 2 – parents, group 3 – students, etc.) and/or for different data collection method (e.g., focus group participants, survey participants, etc.) provide full details on all your informed consent processes.

Be sure to indicate when potential participants will first be provided with the informed consent materials. Consider whether potential participants can be provided with informed consent documents in advance of the first data collection session, so that they have time to consider the nature of their participation and formulate any questions that they have prior to meeting with the researcher. The time required for participants to consider their participation will depend on the magnitude of risks associated with participation as well as the vulnerability of the participants.

Child and Youth Consent/Assent

If you are obtaining informed consent or assent from child or youth participants and informed consent from parents/guardians for the child or youth participants, ensure that both of these processes are fully explained. Be sure to clarify in item 19 how and when children or youth will provide consent/assent and how and when parents/guardians will provide consent for the child or youth participants.

If parents/guardians will not be asked for consent for their child's or youth's participation, clarify why not and describe the process for providing parents/guardians with information about the research study in item O.3.

If parents/guardians will not be asked for consent for their child's or youth's participation, and will not be provided with any information about the research study, clarify why not in item O.3.

Item 20.4: Ongoing Consent

Research may be conducted over more than one session (e.g., two interviews, or one interview plus a review of transcripts) 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 (including transcript review), 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, or verbally confirm consent at each interaction.

Item O.5: 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 N.1 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.⁸

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 you 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 and make it clear that this data will not be used if the participant does not provide this consent. Note that it is not appropriate to ask participants *at the time of initial consent*, to provide this permission for use of their data in the case that they withdraw in the future. The reasons and rationale for withdrawal may impact a participant's decision to allow researchers to use their previously collected data. Thus it is only appropriate to ask permission to allow researchers to use the previously collected data *at the time of withdrawal*.

Ensure the information in item O.5 is consistent with the information provided to participants in the Consent materials.

⁸ If a tracking system (number codes on questionnaires) is used with the implied consent method, this would not be the case.

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 – note this would be a section to be completed only in the case that a participant withdraws
- Ask participants and record their consent to use their data in a research journal/log

** Recommended by the HREB when written consent is used.*

SECTION P. ANONYMITY AND CONFIDENTIALITY

Researchers may wish to review Chapter 5, Privacy and Confidentiality, of the TCPS 2.

Below are explanations of anonymity, confidentiality, exceptions to protecting a person's identity, and privacy.⁹

Anonymity: No one, including the principal investigator, is able to associate responses or other data with the individual participants. Note that for item P.1a this means that the researcher is not aware of the identity of the participants (e.g., submission of an anonymous survey).

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 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 P.1: Anonymity

⁹ The explanations were adapted from the Manual for Community Research Institutional Review Board, Michigan State University.

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 P.2: 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.¹⁰

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: Anonymity and Confidentiality](#), which includes the following topics:

- Limits to confidentiality
- Waiving anonymity and confidentiality

SECTION Q. USE AND DISPOSAL OF DATA

The HREB is responsible for ensuring that research studies:

¹⁰ 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 Article 5.3 of the TCPS.

Q.1: 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 Q.1a describe all the uses which the researchers and research team will have for the data. When responding to items Q.1b - e, 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.

If the data will be kept for possible future uses, consider whether this will be in anonymous or identifiable form. If it is a possibility that you may share identifiable research data with other researchers, at some point in the future, it may not be appropriate to ask participants for consent to this future research at this time, if the other researchers and other study objectives are not yet known. It may be more appropriate to ask participants' permission to contact them again in the future, when full information can be provided to them about the subsequent study and when they will be in a position to provide fully informed consent for the use of their identifiable data. Note that consideration of future uses of personal information refers not just to research, but also to other purposes, such as the future use of research materials for educational purposes – see Article 5.3 of the TCPS 2 for further information.

Q.2: 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 Chapter 7 of the TCPS 2.

Item Q.3: 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. For example, in oral history the best practice may be to archive the information collected (with the participants' consent) for future generations. 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 Article 5.3 of the TCPS 2.

Item Q.4: 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 Article 5.3 of the TCPS 2.

Note that most UVic theses are posted on UVicSpace on the internet so this should be checked in item Q.4 and conveyed to participants in the Consent Form when appropriate.

If you are providing participants or groups involved with the results of the research, indicate here how you will do this and ensure this information is consistent with the information in the Consent Form. For instance, if participants need to provide you with an email address in order to receive the results, ensure you ask for this in the Consent Form.

If there are other ways you plan to disseminate the results of the study, not listed here, explain these in the "other" category.

SECTION R. CONFLICT OF INTEREST

Researchers have an obligation to disclose to participants and the HREB 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. See the TCPS 2, Chapter 7, Conflicts of Interest, for further information.

SECTION S. 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) (template and checklist available on the research ethics 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 the research ethics website)
- Biosafety Approval, or your correspondence with the Biosafety Committee
- Other, as needed.

SECTION T. AGREEMENT AND SIGN-OFF

Submission of the application by the Principal Investigator to the Chair/Director/Dean or their designate indicates Principal Investigator's agreement to abide by all of the University of Victoria regulations, policies and procedures governing the ethical conduct of human research. Researchers are encouraged to review the Faculty manual, the Research Ethics website, and the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS 2) to learn more about what is required. The sign-off/approval by the Chair, Director, Dean or designate indicates that adequate resources are in place within the department or faculty to conduct this research. Please make sure you identify the right individuals to sign-off on your application to avoid any delays. .

Please note that the sign-off must conform to the following:

1. Affirmation required for the following categories/positions:

- The principal investigator
- The department chair, director or the dean OR their designates

Alternatives:

- The same individual may not sign in more than one of the above categories/positions -

If the principal investigator is also the chair, director or dean, sign-off must go one level up, to the person to whom your position reports.

QUESTIONS

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

APPENDIX I - RECRUITMENT

Recruitment of Participants 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.

Please Note: If you are contemplating research in an agency or site that is under the auspices of the Vancouver Island Health Authority (VIHA), involving VIHA staff, patients, health records, sites and/or recruitment through VIHA sites (including recruitment via poster placement), you must use the Joint UVic/VIHA application form. For above minimal risk research, please contact the UVic Research Ethics Office. See Section G in these guidelines for more information.

When reviewing the recruitment process, the HREB 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. For instance, privacy legislation prevents UVic from releasing contact information for staff, students and faculty for research purposes, without prior consent of the UVic staff, students and faculty. 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 6e.iii, you are required to give a rationale for why this recruitment strategy is ethically necessary. Note that this is only a concern when personal or private contact information is used and is not a concern if professional or business contact information is used.

Recruitment using snowball sampling methods

Be sure to explain your snowball sampling methods in item K.1e.ii. Often primary participants are asked to pass on your study information to potential secondary participants, with instructions for those interested to contact you directly. This prevents personal or private contact information for the secondary participants from being released to you without their knowledge or consent. In other cases primary participants may seek and confirm permission of the secondary participants to provide you with their contact information.

Recruitment of First Nations/Indigenous Communities and Persons

The HREB 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 HREB recommends that you consult with the specific communities. Please see Chapter 9 of the TCPS 2 for more information on recruitment of First Nations/Indigenous communities and persons.

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

When reviewing recruitment procedures, the HREB 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 HREB 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.

Influential Relationships

The HREB will also consider your relationship to potential participants in terms of influence and possible pressure to participate that participants may feel. When potential participants are family members, friends, or close professional colleagues, it may not be easy for them to discount your relationship with them when they are considering research participation. While this may not constitute a true “power-over” relationship, safeguards should be considered to prevent any pressure to participate. This should be addressed in item K.1e.v. See the safeguards outlined in Appendix II, for some suggestions.

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/consent form or assent form/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 assent 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 assent 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.

Recruitment of Youth Aged 13 to 16

In most cases, competent youth aged 13 to 16 can provide their own consent in minimal risk studies. Depending on the nature of the study some researchers seek parent/guardian informed consent for the youth involvement while some researchers inform the parents/guardians about the

study without requiring parental/guardian consent. The latter 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 2 states:

Dual roles of researchers and their associated obligations (e.g., acting as both a researcher and a therapist, health care provider, caregiver, teacher, advisor, consultant, supervisor, student or employer) may create conflicts, undue influences, power imbalances or coercion that could affect relationships with others and affect decision-making procedures (e.g., consent of participants). (Article 7.4 “Dual Roles”)

Researchers should separate, to the greatest extent possible, their role as researcher from their other roles as therapists, caregivers, teachers, advisors, consultants, supervisors, employers or the like. If a researcher is acting in dual roles, this fact must always be disclosed to the participant. (Article 3.2)

For a researcher who is in a dual-role (e.g., teacher and researcher), one way to “separate” 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. While it may not be possible to eliminate all conflicts of interest, researchers are expected to identify, minimize or otherwise manage their individual conflicts in a manner that is satisfactory to the REB.¹¹

In item K.2, 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 K.2. Even when the research is of a non-sensitive nature, the HREB 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.

Influential Relationships

Also consider your relationship to potential participants in terms of influence and possible pressure to participate that participants may feel. When potential participants are family members, friends, or close professional colleagues, it may not be easy for them to discount your relationship with them when they are considering research participation. While this may not constitute a true “power-over” relationship, safeguards should be considered to prevent any pressure to participate. This should be addressed in item 6e.v.

¹¹ TCPS 2, Chapter 7, section A

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 for power-over relationships. The HREB 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 HREB 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 HREB 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 you have explained how you will prevent inducement, pressure and coercion during the recruitment stage of the research.

APPENDIX III – SELF-REFLECTIVE AND EMERGENT RESEARCH

A Note about Self-Reflective Research

If you are conducting self-reflective research, such as an autoethnography or an autobiographical study, please check the box marked “other” in item L.1a and identify and explain your research method. For self-reflective research, the main ethical concern is that individuals may be identified within the research work without their knowledge and/or consent. (For more information see Section M: Risks). In self-reflective research, the HREB recommends you anticipate that in your research you may wish to include information about a person that may identify him/her and to include a consent form to cover this situation should it arise. You would include this information under the “informed consent” section in the Research Ethics Application Form. You should anticipate the possibility that you may directly or indirectly provide information about an identifiable person (e.g., a spouse, a parent etc). This should be clarified in section P: Anonymity and Confidentiality. To minimise harm to such individuals, you should obtain their consent in advance and allow them to view sections of the research report that include information about them, with permission to ask that sections they perceive as harmful to them be removed.

A Note about Emergent Research

For multi-method or other complex research (e.g., community-based research, participatory action research), answer section L 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 HREB can adequately assess the research ethics issues pertaining to your particular study. The HREB 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 HREB 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 modifications (or amendments) submitted to the HREB.

If you are doing multi-phased or community-based research and you cannot provide complete information in the Research Ethics Application Form, complete all items to the best of your ability and include the information that you will be seeking subsequent modification applications as your projects take 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 Research Ethics Application Form you must describe the general direction/subject matter of the questions and state that you will submit a modification application to have the questionnaire reviewed and approved by the HREB prior to implementing it. For further information, see Chapter 10 of the TCPS 2. If after reviewing this information, you have specific questions, please contact the Research Ethics Office at 250-472-4545 or ethics@uvic.ca for assistance. In item L.1c, 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 L.1d 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 HREB frequently requires researchers to make revisions to their Research 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 HREB 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 Research Ethics Application Form.

A Word About Risks to Employment

Another frequent reason why researchers are required to make revisions to the Research 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 Research Ethics Application Form.

APPENDIX V – INFORMED CONSENT

Exceptions to General Guidelines for Children and Youth

The HREB 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.

Competent children under age 13 years for Minimal Risk Studies

- For minimal risk studies, normally competent children under age 13 years give their own assent or consent to participate and parents/guardians provide consent
- 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-rules consent given by others; if a child chooses not to participate, this must be respected no matter who else has consented to the child's participation. 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 assent 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 assent 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 may not be 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 parents/guardians due to the nature of the study and/or the obligation to protect the privacy and confidentiality of the potential participants.

Note that there may be reasons why asking for parental consent of this age group is appropriate and/or required. For instance, school districts may require parental consent when children of any age are recruited through schools.

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.

Note that there may be reasons why asking for parental consent of this age group is appropriate and/or required. For instance, school districts may require parental consent when children of any age are recruited through schools.

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 for research participation, and to appreciate the potential consequences of their decision to participate or not participate, 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. See the TCPS 2, Chapter 3; section C, for further information.

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/Interviews

When obtaining consent for telephone surveys or interviews, in minimal risk research, the HREB may accept the use of a verbal consent script, which contains all the relevant information normally included in a consent form, but which is provided verbally to the participant.

Wherever possible, a written copy of the consent script, 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 or interview, 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 minimal risk 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 HREB 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.¹² The implied consent process may state something like: "By completing and submitting the questionnaire, YOUR FREE AND INFORMED CONSENT IS IMPLIED and indicates that you understand the above conditions of participation in this study and that you have had the opportunity to have your questions answered by the researchers."

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 19 which the HREB will examine very carefully. Before deciding to exclude the process of informed consent, please consider the information below.

Alteration of Consent in Minimal Risk Research

As outlined in Article 3.7 of the TCPS 2, the HREB may approve research without requiring that the researcher obtains the participant's consent in accordance with Articles 3.1 to 3.5, provided that the REB is satisfied with the researcher's reasoning, and it has been documented that all of the following apply:

¹² 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.

- (a) the research involves no more than minimal risk to the participants;
- (b) the lack of the participant's consent is unlikely to adversely affect the welfare of the participant;
- (c) it is impossible or impracticable to carry out the research and to answer the research question properly, given the research design, if the prior consent of the participant is required;
- (d) whenever possible and appropriate, after participation, or at a later time during the study, participants will be debriefed and provided with additional pertinent information in accordance with Articles 3.2 and 3.4, at which point they will have the opportunity to refuse consent in accordance with Article 3.1; and
- (e) the research does not involve a therapeutic intervention, or other clinical or diagnostic interventions.

Normally researchers who plan to examine personal records or files that contain identifying information 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 HREB may accept researchers accessing information from such records without free and informed consent from the individuals if the information is extracted and provided to the researchers 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;
- Are conducted in an open setting (e.g., parking lot or public park); and
- There is no reasonable expectation of privacy by those who are being observed

However, an application for use of anonymized data/biological materials must be submitted to the HREB prior to commencing such research. If the study meets the above requirements for an anonymized application, 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 HREB 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 to the TCPS:

Consent is not required from organizations such as corporations or governments for research about their institutions, when the information about the organization is available publicly. 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.

Organizational approval is required by the HREB when participants are being recruited through an organization. However, if the participants are not being recruited via an organization, the HREB 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 Research 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.

A note about Internet Data Collection

Research that relies exclusively on information that is publicly available may be eligible for a Application for use of anonymized data/biological materials.¹³ Even identifying information may be disseminated publicly with no reasonable expectation of privacy on the part of those for whom the information is about. However there are publicly accessible digital sites where there is a reasonable expectation of privacy. For instance if users of the site must create a login or represent themselves in a certain way (consider Internet chat rooms, and self-help groups with restricted membership, or sites where users must login to gain access to certain information), the privacy expectation of contributors to these sites is much higher. In these cases researchers should complete the standard research ethics application and clarify how they will seek informed consent from their participants.

¹³ Please see the "Application for use of anonymized data or biological materials" available on the Research Ethics website.

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 Research Ethics Office.

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 P.2:

- 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?
- Will there be data sharing and/or data storage in other countries such that local legislation could impact the confidentiality of the research data (consider, for instance, if there will be data storage in the USA, with the consequence that the data then will be subject to the US Freedom Act).

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 and respect their wishes as to what will be done with their data in the case that they withdraw.