

NEW BEHAVIOURAL APPLICATION FORM

(Effective 15 December 2012)

The following pages provide an overview of the new behavioural ethics application form. On December 15th, this application replaced the existing behavioural application form. There are some important areas of difference between the existing and new forms. These include the following:

General changes

- Although Views 1-4 on the form are shared with the clinical application form, in other parts of the application an effort has been made to remove the clinical orientation of the existing form (e.g., questions about 'controls', the assumption that research will take place in a clinical setting, use of terms like 'protocol', etc.)
- Questions have also been tailored to better suit social science and behavioural research (e.g., the introduction of a new question of research impacts on the community; shift from a focus on consent forms to documenting consent – which might occur in a variety of ways, etc.)

Specific changes

The most substantive changes to the form occur in View 4* of the application. These include:

- The expansion of the question on minimal risk (4.5), asking applicants to determine where their study lies on the minimal risk matrix and to justify their ranking.
- A new question about multi-jurisdictional studies (4.6), where review from several Canadian REBs is required. If you respond "yes" to this question, you will be directed to a branch off from the main application form that asks you more detailed questions. Depending on how you respond to these questions, you may need to: a) fill out the full application or b) fill out a truncated version of the application.
- A new question about the creation of a research database for non-specified future research purposes (4.7). If you respond "yes" to this question, you will be directed to a branch off from the main application form that asks you more detailed questions about the database. If your application is exclusively to create such a database, the application will truncate to View 9. If the creation of the database forms one component of the application, you will need to fill out the full application to describe the other components of the study.
- If you are submitting an application to the UBC Behavioural Ethics Board or UBC Okanagan Behavioural Ethics Board, you will also see a new question about class projects (4.8). If you are submitting an application for a class project you will no longer have to fill out the 'class project form' and attach it to View 9. Instead, this form has been incorporated into the RISE application as a branch off from the main form. When you've filled out this branch off, the application form will then truncate to View 9.

If you have questions about the new application form, please contact Dr Kirsten Bell, Consultant Research Ethics Analyst, Office of Research Ethics (email: Kirsten.bell@ors.ubc.ca; ph: 604 872 5310; general availability: Wednesday-Friday).

VIEW 1

1. PRINCIPAL INVESTIGATOR & STUDY TEAM - HUMAN ETHICS APPLICATION

* 1.1. Principal Investigator

Please select the Principal Investigator (PI) for the study. Once you hit "Select", you can enter the PI's name, or enter the first few letters of his or her name and hit "Go". You can sort the returned list alphabetically by First name, Last name, or Organization by clicking the appropriate heading.

Primary Appointment:
Rank:
Email:

Enter Principal Investigator Primary Department and also the primary location of the PI's Institution:

1.2. Primary Contact

Provide the name of ONE primary contact person in addition to the PI who will receive ALL correspondence, certificates of approval and notifications from the REB for this study. This primary contact will have online access to read, amend, and track the application.

Primary Appointment:
Rank:
Email:

GUIDANCE NOTES

A Principal Investigator (PI) either has a faculty appointment (Clinical Assistant Professor, Clinical Associate Professor, Clinical Professor, Assistant Professor, Associate Professor, Professor or BCCA Investigator) OR is deemed a PI by an affiliated institution or by a Dean.

The PI bears the overall responsibility for the conduct of the study and is required to act within the guidelines of the [TCPS2](#).

Instructors who are applying for research ethics approval for class-based projects in courses they are teaching can be listed as a PI on their application. Please contact the REB manager if you are submitting a class project and require the capacity to list yourself as a PI on the application.

If you cannot find the PI's name in the list, have it added into the RISE system by emailing the following information to [RISe Support](#): Full Name (Including Middle Initial), Department (or affiliation with the University), UBC Rank, Email Address, Phone Number and UBC employee number (if applicable). Once an account is created, new users will receive their researcher number via email.

Selecting a primary contact is optional. If a primary contact is not selected, the PI will be the only person to receive all correspondence from the Research Ethics Board Administration (REBA). Graduate students preparing ethics applications for their dissertation projects should list themselves as the primary contact. The Primary Contact may also be listed in one of the categories below. Note that the PI may change the Primary Contact anytime without an amendment.

<p>Study Team Members</p> <p>Complete sections 1.3, 1.4 and 1.5 below to add Co-Investigators and additional study team members and to designate the type of online access you would like them to have.</p> <p><i>To add</i> Co-Investigators and additional study team members in questions 1.3 and 1.4:</p> <ol style="list-style-type: none"> 1. Click "Add". 2. Enter the name, or enter the first few letters of the person's name and click "Go". 3. You can sort the returned list alphabetically by First name, Last name, or Organization by clicking the appropriate heading. 4. Select the boxes beside ALL applicable names and click "OK". <p><i>To delete</i> a person from the list, select the box next to his or her name and click "Remove".</p> <p>1.3. Co-Investigators</p> <p>List all the Co-Investigators of the study. These members WILL have online access which will allow them to read, amend and track the application. These members will be listed on the certificate of approval (except BC Cancer Agency Research Ethics Board certificates). If this research application is for a graduate degree, enter the graduate student's name in this section.</p> <div data-bbox="66 1123 792 1312"> <input type="text"/> <table border="1"> <thead> <tr> <th>Last Name</th> <th>First Name</th> <th>Institution/Department</th> <th>Rank</th> </tr> </thead> <tbody> <tr> <td colspan="4">There are no items to display</td> </tr> </tbody> </table> </div>	Last Name	First Name	Institution/Department	Rank	There are no items to display				<p>Please make sure you have added yourself as either the Principal Investigator, primary contact, co-investigator, or a study team member with online access in order to continue with the application.</p> <p>If you cannot find your name or any of your study team members' names in the list, have them added or inform them to add themselves by emailing the following information to RISE Support(risesupport@ors.ubc.ca): Full Name (Including Middle Initial), Department (or affiliation with the University), UBC Rank, Email Address, Phone Number and UBC employee number (if applicable). Once an account is created, new users will receive their researcher numbers via email.</p> <p>If you are applying to the BC Cancer Agency (BCCA), co-investigators will not be listed on the certificates of approval; however, all participating BCCA centre PIs will be listed. You will be asked to enter the BCCA centre PI's names in View 11. For further information click here for the BCCA Research Ethics Board policy.</p>
Last Name	First Name	Institution/Department	Rank						
There are no items to display									
<p>1.4. Additional Study Team Members - Online Access</p> <p>List the additional study team members who WILL have online access to read, amend, and track the application but WILL NOT be listed on the certificate of approval.</p> <div data-bbox="66 1480 792 1640"> <input type="text"/> <table border="1"> <thead> <tr> <th>Last Name</th> <th>First Name</th> <th>Institution/Department</th> <th>Rank</th> </tr> </thead> <tbody> <tr> <td colspan="4">There are no items to display</td> </tr> </tbody> </table> </div>	Last Name	First Name	Institution/Department	Rank	There are no items to display				<p>Examples of additional study team members who you may wish to have online access to the application include Clinical Trial Coordinators and Research Assistants.</p>
Last Name	First Name	Institution/Department	Rank						
There are no items to display									
<p>1.5. Additional Study Team Members - No Online Access</p>	<p>The study team members listed in this</p>								

<p>Click "Add" to list study team members who WILL NOT have online access to the application and will NOT be listed on the certificate of approval.</p> <table border="1"> <thead> <tr> <th>Last Name</th> <th>First Name</th> <th>Institution/Department</th> <th>Rank/Job Title</th> <th>Email Address</th> </tr> </thead> <tbody> <tr> <td colspan="5">There are no items to display</td> </tr> </tbody> </table>	Last Name	First Name	Institution/Department	Rank/Job Title	Email Address	There are no items to display					<p>section do not have online access to RISE. Please print off the application and ensure that each member listed in this section has read and understood the objectives and procedures of this study.</p>
Last Name	First Name	Institution/Department	Rank/Job Title	Email Address							
There are no items to display											
<p>1.6. Tri Council Policy Statement (TCPS) Tutorial</p> <p>* Tri Council Policy Statement2 (TCPS2) Tutorial <i>All undergraduate and graduate students and medical residents are required to complete the TCPS2 Tutorial (CORE) before submission. This tutorial provides an essential orientation to Canadian human research ethics guidelines. The Principal Investigator and all Co-Investigators must be familiar with the TCPS2. Indicate completion of the TCPS2 (CORE) tutorial below:</i></p> <p>1.6.A. All Undergraduate/Graduate Students:</p> <p><input checked="" type="radio"/> N/A (no undergraduate/graduate students participating in this study)</p> <p><input type="radio"/> No</p> <p><input type="radio"/> Yes Clear</p> <p>* 1.6.B. All Medical Residents:</p> <p><input checked="" type="radio"/> N/A (no medical residents participating in this study)</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No Clear</p> <p>Comments:</p>	<p>All non-Faculty personnel who are associated with a research project and who will have contact with the research participants are required to complete the TCPS2 online tutorial (CORE) before the application is submitted to the REB. This includes (but is not limited to) undergraduate and graduate students, medical residents, research assistants, research coordinators, etc. The REB requires that all Principal Investigators be familiar with the TCPS2 and recommends that Principal Investigators also complete the TCPS2 tutorial, especially when the Principal Investigator supervises or teaches classes for graduate students or medical residents.</p> <p>The TCPS CORE Tutorial is free and can be completed in about two hours. CORE Certificates do not need to be attached. Copies should be retained by the PI and be available on request.</p> <p>Click here for the TCPS2 Document. Click here for the TCPS2 'CORE' Tutorial.</p>										

	
<p>* 1.7. Project Title</p> <p><i>Enter the title of this research study as it will appear on the certificate. If applicable, include the protocol number in brackets at the end of the title. If this is a class-based project, see guidance on the right.</i></p> 	<p>The title given in the application form must correspond to the title on all study documents, including the consent form.</p> <p>If the study is supported by research grant or contract funding that is being administered by the University or one of the teaching hospitals, the title should correspond to the title on the grant or contract.</p> <p>For studies that have multiple titles that correspond with multiple funding sources, please enter these titles and the respective funding sources in question 2.4.</p> <p>For class-based projects please ensure to include "Class Project" in the first part of the title and the project nickname (question 1.8).</p>
<p>* 1.8. Project Nickname</p> <p><i>Enter a nickname for this study. What would you like this study to be known as to the Principal Investigator and study team?</i></p> 	<p>The nickname will not be printed on the certificate. It will be used throughout the online application and review process to serve as a quick reference to identify the project.</p> <p>For class-based projects, include "Class Project" in the first part of the nickname.</p> <p>For Family Practice Residency projects, include "Family Practice Project" in the first part of the nickname.</p> <p>For Harmonized Review projects include "Harmonized Review Project" in the first part of the nickname.</p>

VIEW 2

2. STUDY DATES & FUNDING INFORMATION - HUMAN ETHICS APPLICATION

Project Period

*** 2.1.A.**

Please choose **ONE** of the following:

- You plan to start collecting data immediately after obtaining ethics and any other required approvals (the start date on the ethics certificate will reflect the approval date),



OR

- You plan to start data collection at a later date i.e., 2 months or more after approvals are obtained. Click the calendar icon below to select the dates (Internet Explorer) or enter the dates manually using the format yyyy-mm-dd.

Estimated start date:

*** 2.1. B.**

Estimated end date:

In multi-phase projects, include the period that involves research with human participants.

Source of Funds

*** 2.2.A. Types of Funds**

Please select the applicable box(es) below to indicate the type(s) of funding you are receiving to conduct this research. **You must then complete section 2.3 and/or section 2.4 for the name of the source of the funds to be listed on the certificate of approval.**

Type(s) of Funding

Grant

No Funding

Grant-in-aid

For-Profit Sponsor (Industry or Pharmaceutical)

"Source of Funds" refers to the funder, sponsor, grantor, or agency (government, industry, and non-profit) that is providing the funds needed to undertake the project. Note that you should not indicate that your study is "For Profit" if a sponsor is only collaborating and not funding the study, e.g., they are providing the study drug or laboratory space only.

<input type="checkbox"/> Internal Funds <input checked="" type="checkbox"/> Other (Enter details in 2.3 or 2.4 as appropriate) 2.2.B. For Industry Sponsored studies, please provide a sponsor contact. <div style="border: 1px solid #ccc; height: 40px; width: 100%;"></div>									
<p>Source of Funds</p> <p>Please clearly identify the application for research funding associated with this ethics application. This will ensure that awarded research funds can be made available to you once this ethics application receives approval.</p> <p>2.3. Research Funding Application/Award Associated with the Study that was Submitted to the UBC Office of Research Services</p> <p>Please click "Add" to identify the research funding application/award associated with this study. Selecting "Add" will list the sources of all research funding applications that have been submitted by the PI (and the person completing this application if different from the PI). If the research funding application/award associated with this study is not listed below, please enter those details in question 2.4.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 20%;">UBC Number</th> <th style="width: 30%;">Title</th> <th style="width: 20%;">Funding PI</th> <th style="width: 30%;">Sponsor</th> </tr> </thead> <tbody> <tr> <td colspan="4" style="text-align: center;">There are no items to display</td> </tr> </tbody> </table>	UBC Number	Title	Funding PI	Sponsor	There are no items to display				<p>Question 2.3 lists the research funding applications/awards that have been submitted to the UBC Office of Research Services and entered into our database. Identifying the associated research funding application/award will ensure that awarded research funds will be made available to you once this ethics application receives approval.</p> <p>Please ensure you select the correct application. Note that the first two digits of the application number indicate the year the application was submitted (e.g., Application #F08-00001 was submitted in 2008).</p>
UBC Number	Title	Funding PI	Sponsor						
There are no items to display									
<p>2.4. Research Funding Application/Award Associated with the Study not listed in question 2.3.</p> <p>Please click "Add" to enter the details for the research funding application/award associated with this study that is not listed in question 2.3. When you press "Add" you can do a search for your funding award by doing a search in the "Sponsor" box - over 7000 options are listed</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%;">Title</th> <th style="width: 50%;">Sponsor</th> </tr> </thead> <tbody> <tr> <td colspan="2" style="text-align: center;">There are no items to display</td> </tr> </tbody> </table>	Title	Sponsor	There are no items to display						
Title	Sponsor								
There are no items to display									
<p>U.S. Funding</p> <p>* 2.5.A. Is this a DHHS grant? (To view a list of DHHS funding agencies click on "add" in 2.5.B below)</p>	<p>The Department of Health and Human Services, DHHS (US Federal Agencies), requires the Research Ethics Board to review the actual grant</p>								

<p> <input checked="" type="radio"/> Yes <input type="radio"/> No Clear </p> <p>2.5.B. <i>If yes, please select the appropriate DHHS funding agency from the selection box, and attach the grant to box 9.8. of the application.</i></p> <p>DHHS Sponsor List</p> <p>Agency for Toxic Substances & Disease (ATSDR)</p> <p>Attach DHHS Grant Application for each sponsor listed above</p> <p>Title</p> <p>ubcLogo.gif</p>	<p>application to compare it to the protocol being approved, to ensure that they are the same. Your certificate of approval will not be released until this documentation is attached.</p>
<p>* 2.6. Conflict of Interest</p> <p><i>Do any of the following statements apply to the Principal Investigator, Co-Investigators and/or their partners/immediate family members?</i></p> <ul style="list-style-type: none"> • <i>Receive personal benefits in connection with this study over and above the direct cost of conducting this study. For example, being paid by the funder for consulting. (Reminder: receiving a "finders fee" for each participant enrolled is not allowed).</i> • <i>Have a non-financial relationship with the sponsor (such as unpaid consultant, advisor, board member or other non-financial interest).</i> • <i>Have direct financial involvement with the sponsor (source of funds) via ownership of stock, stock options, or membership on a Board.</i> • <i>Hold patent rights or intellectual property rights linked in any way to this study or its sponsor (source of funds).</i> <p> <input type="radio"/> Yes <input checked="" type="radio"/> No Clear </p>	<p>The REB needs to be satisfied that participants are informed of conflict of interest matters in the consent process. Note that "immediate family members" includes partners and children (whether living in the household or not). The REB does not require that the investigator identify holdings in managed mutual funds to be declared in the conflict of interest statements. If you answer yes to this question you will be asked to provide more detail on view 3 of the application.</p>

VIEW 4

4. STUDY TYPE - HUMAN ETHICS APPLICATION

* 4.1. UBC Research Ethics Board

Indicate which UBC Research Ethics Board you are applying to and the type of study you are applying for:

Research Ethics Boards
<input type="radio"/> BC Cancer Agency Research Ethics Board - Clinical
<input type="radio"/> BC Cancer Agency Research Ethics Board - Behavioural
<input type="radio"/> Children's and Women's Research Ethics Board - Clinical
<input type="radio"/> Children's and Women's Research Ethics Board - Behavioural
<input type="radio"/> Providence Health Care Research Ethics Board - Clinical
<input type="radio"/> Providence Health Care Research Ethics Board - Behavioural
<input type="radio"/> UBC Okanagan Behavioural Research Ethics Board
<input type="radio"/> UBC Behavioural Research Ethics Board
<input checked="" type="radio"/> UBC Clinical Research Ethics Board
Clear

UBC's REBs have signed a one board of record agreement. Studies taking place at multiple UBC sites require review and approval by only one UBC-Affiliated REB. Choice of Board should be determined by the PI's primary appointment and/or the main location of the research.

Clinical projects are those involving surgery, the administration of drugs, medical imaging or other diagnostic techniques, biopsies, the taking of blood or other specimens, the review of clinical medical records, and any invasive procedure. A clinical research project that also includes questionnaires or interviews should be submitted to a Clinical Research Ethics Board.

Behavioural projects are those that are behavioural or social scientific in nature or involve humanities research. They may involve the study of patients or healthcare providers; however, they are not clinical and do not involve invasive procedures. They do include research involving interviews, observations, and the administration of questionnaires or tests.

* 4.2. Institutions and Sites for Study

Enter the locations for the institutions and sites where the research will be carried out under this Research Ethics Board approval (including specimens processed by pathology, special radiological procedures, specimens obtained in the operating room, or tissue requested from pathology).

If your research will not be carried out at an institutional site, please check the "N/A" box. Otherwise click "Add" and enter the appropriate letter to see the locations for the institutions and sites where the research will be carried out under this Research Ethics Board approval: B for BC Cancer Agency C for Children's and Women's Health Centre of BC P for Providence Health Care U for UBC Campus V for Vancouver Coastal Health (VCHRI/VCHA).

N/A:

4.2.A. Institutions and Sites for Study

Hospital/Institution	Site

There are no items to display

4.2.B.

Please enter any other locations where the research will be conducted under this Research Ethics Approval (e.g., private physician's office, community centre, school, classroom, participant's home, in the field - provide details).

A scrollable text input field with a vertical scrollbar on the right and horizontal scrollbars at the bottom.

VIEW 4*

4*. BEHAVIOURAL STUDY REVIEW TYPE - HUMAN ETHICS APPLICATION

Relationship to Previous Ethics Applications

4.3.A.

If this proposal is closely linked to any other proposal previously/simultaneously submitted, enter the Research Ethics Board number of that proposal.

4.3.B.

If applicable, please describe the relationship between this proposal and the previously/simultaneously submitted proposal listed above.

4.3.C.

Have you received any information or are you aware of any rejection of this study by any Research Ethics Board? If yes, please provide known details and attach any available relevant documentation in question 9.7.

Yes No [Clear](#)

Indicate whether the study is an extension or a sub-study of a primary study or if the study is utilizing data collected under a previous study.

A sub-study is a concurrent study on a sub-sample/population of the original study sample/population.

If a study has been rejected by another UBC-affiliated REB, it may not be re-submitted to any other UBC-affiliated REB.

Peer Review

If this research proposal has received any independent scientific/methodological peer review, please include the names of committees or individuals involved in the review. State whether the peer review process is ongoing or completed.

* 4.4.A.

External peer review details:

According to [Article 2.7](#) of the TCPS2, "Research in the humanities and social sciences that poses, at most, minimal risk shall not normally be required by the REB to be peer reviewed".

For research posing more than minimal risk, the REB recognizes that an independent peer review may be either 'internal' or 'external'. The appropriate type of review is dependent on the nature of the study.

For graduate student projects submitted to the BREB, the approval of the supervisory committee is deemed to constitute sufficient peer review.

If you have any peer review reports attach them to section 9.7 of the RISE

application.

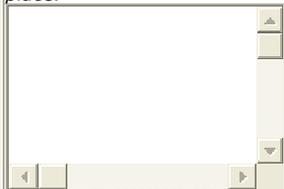
*** 4.4.B.**

Internal (UBC or hospital) peer review details:



*** 4.4.C.**

If this research proposal has NOT received any independent scientific/methodological peer review, explain why no review has taken place.



Minimal Risk

*** 4.5.A**

*After considering the level of risk your research involves and the vulnerability of your study population, please tick **one** box below that best*

The TCPS2 defines minimal risk as:
"research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that

represents the overall level of risk your study entails.

Group Vulnerability	Research Risk		
	Low	Medium	High
Low	1 <input checked="" type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>
Medium	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>
High	2 <input type="checkbox"/>	3 <input type="checkbox"/>	3 <input type="checkbox"/>

Please check **one** box only

*** 4.5.B**

Explain/justify the level of risk and group vulnerability reported above.

*** 4.5.C**

Does your application fall under "minimal risk" (i.e., it was assigned an overall risk level of 1 on the minimal risk matrix) and therefore is eligible to be considered for Delegated Review?

Yes No [Clear](#)

*** 4.6. Harmonized Review of Multi-Jurisdictional Studies**

Is this study a **multi-jurisdictional** study that requires review by one or more institutions?

Yes No [Clear](#)

4.7.A Creation of a Research Database or Registry

relate to the research".

In considering whether your study is minimal risk you should consider **participant vulnerability** and the **research risk** itself. Vulnerability is "A diminished ability to fully safeguard one's own interests in the context of a specific research project" (TCPS2, p. 197). Considerations of research risk should factor in the type of potential harm that might result (e.g. psychological or informational), the magnitude or seriousness of the harm (e.g. transient or permanent), and the probability of occurrence of the harm (e.g. likely or remote).

If your study involves a low vulnerability group and low/medium research risk, or low research risk and a low/medium vulnerability group, it is assigned an overall risk level of **1** and falls under the "minimal risk" category.

Click [here](#) for further information on the risk matrix and minimal risk criteria.

A multi-jurisdictional study is a research study that requires review and approval by more than one Canadian research ethics board (i.e., by more than one Canadian REB as well as a UBC affiliated REB) as a result of the requirements of the TCPS2 and/or UBC's and/or another institution's human ethics policies.

When you click "Yes" to question 4.6 you will be directed to a branch off which asks specific questions about multi-jurisdictional studies.

Research databases or registries are repositories that collect and store

Comment [A1]: BEHAVIOURAL BOARDS:
If you answer "yes" to this question, you will be taken to View F (see page 43). Depending on how you answer the questions in View F, the application form may truncate to View 9 or you may be directed back to View 5 of the application.

HOSPITAL BOARDS:
If you answer "yes" to this question, you will be taken to View E (see page 57 of the clinical form). Depending on how you answer the questions in View E, the application form may truncate to View 9 or you may be directed back to View 5 of the application.

<p>Does this study involve the creation of a research database or registry for future unspecified research? [if no, skip to 4.8]</p> <p><input checked="" type="radio"/> Yes <input type="radio"/> No Clear</p> <p>4.7.B</p> <p>Is the purpose of this application exclusively to obtain approval for the creation of a research database or registry? [Note: if the creation of the database or registry is part of a bigger project also included in this application, you must answer "no" below].</p> <p><input checked="" type="radio"/> Yes <input type="radio"/> No Clear</p>	<p>information about humans specifically for future unspecified research purposes. The information may or may not include personally identifying information, test results, information about ethnicity, age, or place of origin, etc., that is collected retrospectively or prospectively.</p> <p>Wanting to use routinely collected teaching or program evaluation data for future unspecified research purposes would fall into this category.</p> <p>When you click "Yes" to question 4.7.A you will be directed to a branch off which asks specific questions about the registry or database you are creating. If your application is exclusively to obtain approval for the creation of the database or registry, the application will truncate and you will be directed to view 9. If the creation of the database is only one component of the application, you will need to fill out views 5-8.</p>
<p>4.8. Class-based research and the department level research ethics review process</p> <p>Is this study a minimal risk class-based research project conducted for pedagogical purposes, e.g., a research methods course exercise, or other exercises designed to give students training in conducting and/or presenting research? The activity should not be an undergraduate or graduate thesis/dissertation.</p> <p><input checked="" type="radio"/> Yes <input type="radio"/> No Clear</p> <p>If "Yes", please state whether your department has a Departmental Ethics Officer (DEO) and, if so, indicate their name below.</p> <input type="text"/>	<p>Please click here for the class project guidelines to ensure that your proposed project fits the parameters of the class project framework. When you click "Yes" to question 4.8 you will be directed to a branch off: the class project application form. The application will then truncate and you will be directed to view 9.</p> <p>Note: If your department has a Departmental Ethics Officer (DEO), then this application will be sent to them for review. If your department does not have a DEO, then it will be reviewed through the BREB's normal minimal risk review channels. Click here for further information about the BREB's Department-level research ethics review process and for examples of what types of projects qualify for review at the department level.</p>

Comment [A2]: BEHAVIOURAL BOARDS:
If you answer "yes" to this question you will be taken to View B (see page 31).

HOSPITAL BOARDS:
If you answer "yes" to this question you will be taken to View C (see page 47 of the clinical application form).

Comment [A3]: If you answer "yes" to this question, the application will truncate to View 9. If you answer "no" to this question, you will be directed back to View 5 of the application.

Comment [A4]: This question will only appear on applications submitted to the UBC Behavioural Research Ethics Board and the UBC Okanagan Behavioural Research Ethics Board

Comment [A5]: If you answer "yes" to this question, you will be taken to View D (see page 38). This view contains essentially the same information as the class project application form which currently has to be attached to View 9 of the application. Because this information is now integrated into the application itself, you will no longer need to attach the form. The application will truncate to View 9 and you just need to provide other attachments (e.g., course outline, assignment guide, consent templates, etc.)

To save information on each view as you are working, especially if you are working on the view for a long period of time, select the "Save" button located at the top or bottom of the view in the blue bar. Your work on each view will automatically be saved once you hit the "Continue" button.

VIEW 5

5. SUMMARY OF STUDY AND RECRUITMENT - HUMAN ETHICS APPLICATION

Please note that all required fields are marked with a red asterisk and need to be filled out before being able to proceed onto the next page. Please make sure to save your work before continuing onto the next page in an effort to make sure your work is not lost. You can do so by clicking on the **"Save"** link at the top or the bottom of this page.

Study Summary

5.1.A

Provide a short summary of the project written in lay language suitable for non-scientific REB members. DO NOT exceed 100 words and do not cut and paste directly from the study proposal.

A text input field with a light beige background and a vertical scrollbar on the right side. The field is currently empty.

* 5.1.B

Summarize the research proposal:

A text input field with a light beige background and a vertical scrollbar on the right side. The field is currently empty.

The summary should include the following: the research question and/or hypothesis (where and if a hypothesis is appropriate to the study), the study population, and the study methods.

The REB will review the study proposal attached to question 9.1 for the expanded description of how the study aims will be achieved and how the analysis will be undertaken. The board's main interest here is what the researcher will actually be doing with participants as he/she undertakes the study so that they can assess potential risks to the participants and how the researcher is handling them, etc.

Describe the purpose in lay language or include definitions of jargon or technical terms. Also, all acronyms must be written out in full the first time that they appear in the application form, recruiting and consent materials.

5.2. Inclusion Criteria

Describe the participants being selected for this study, and list the criteria for their inclusion.

A text input field with a light beige background and a vertical scrollbar on the right side. The field is currently empty.

Please enter the inclusion criteria as an itemized list.

The selection of participants must take TCPS2 [article 4.1](#) into consideration, which states that "Taking into account the scope and objectives of their research, researchers should be inclusive in selecting research participants". However, the TCPS2 cautions against recruiting participants into research studies solely because they are easy to access or manipulate.

5.3. Exclusion Criteria

Describe which participants will be excluded from participation, if any, and list the criteria for their exclusion.



If applicable, provide all exclusion criteria. If not applicable, write "N/A".

Article 4.1 of the TCPS2 states that "researchers shall not exclude individuals from the opportunity to participate in research on the basis of attributes such as culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender or age, unless there is a valid reason for the exclusion". Provide justification for excluding participants on the basis of such attributes.

Please enter the exclusion criteria as an itemized list.

5.4. Recruitment

Provide a detailed description of the method of recruitment. For example, describe who will contact prospective participants and by what means this will be done. Ensure that any letters of initial contact or other recruitment materials are attached to this submission on view 9 (section 9.7).



Privacy legislation in BC states that organizations cannot provide contact information for clients without their consent unless the researchers have obtained permission from the Provincial Privacy Commissioner.

Click [here](#) for information on **recruitment**.

UBC policy does not allow initial contact by telephone. However, surveys which use random digit dialing may be allowed. If your study involves initial contact by random digit dialing, please click [here](#) to complete the Telephone Contact Form, then save and attach the form to question 9.6.

5.5. Use of Records

If existing records (e.g., health records, course grade sheets or other records/databases) will be used to IDENTIFY potential participants, please describe how permission to access this information, and to collect and use this information, will be obtained.



Where the investigator is in a dual relationship - that is, the researcher maintains the records (e.g., as a clinician, educator, etc.) and is proposing to undertake research on them, steps need to be taken to ensure participants' rights are not violated.

<p>* 5.6. Summary of Procedures</p> <div style="border: 1px solid gray; height: 200px; width: 100%;"></div>	<p>Describe in a step-by-step manner the research procedures. If the study involves an experimental approach to curriculum or therapy, specify how the procedures differ from normal practice. If Deception is involved, please click here to complete the Deception Form, then save and attach the form to question 9.7.</p>														
<p>5.7. Checklist for Research Methods</p> <p><i>Are any of the following procedures or methods involved in this study? Check all that apply.</i></p> <table border="1" style="width: 100%;"> <tr><td><input type="checkbox"/> Action Research</td></tr> <tr><td><input type="checkbox"/> Autobiography/Auto-Ethnography</td></tr> <tr><td><input type="checkbox"/> Data Linkage</td></tr> <tr><td><input type="checkbox"/> Deception</td></tr> <tr><td><input type="checkbox"/> Ethnographic Fieldwork</td></tr> <tr><td><input type="checkbox"/> Expert Interviews</td></tr> <tr><td><input type="checkbox"/> Focus Groups</td></tr> <tr><td><input type="checkbox"/> Naturalistic Observation</td></tr> <tr><td><input type="checkbox"/> Random Digit Dialing</td></tr> <tr><td><input type="checkbox"/> Secondary Use of Data</td></tr> <tr><td><input type="checkbox"/> Subject Pools</td></tr> <tr><td><input type="checkbox"/> Use of Medical Records</td></tr> <tr><td><input type="checkbox"/> Videotaping</td></tr> <tr><td><input type="checkbox"/> None of these Methods</td></tr> </table>	<input type="checkbox"/> Action Research	<input type="checkbox"/> Autobiography/Auto-Ethnography	<input type="checkbox"/> Data Linkage	<input type="checkbox"/> Deception	<input type="checkbox"/> Ethnographic Fieldwork	<input type="checkbox"/> Expert Interviews	<input type="checkbox"/> Focus Groups	<input type="checkbox"/> Naturalistic Observation	<input type="checkbox"/> Random Digit Dialing	<input type="checkbox"/> Secondary Use of Data	<input type="checkbox"/> Subject Pools	<input type="checkbox"/> Use of Medical Records	<input type="checkbox"/> Videotaping	<input type="checkbox"/> None of these Methods	<p>This does NOT represent a comprehensive list of research methods. These methods are included here because they represent possible departures from established processes for obtaining free and informed consent. Therefore, please do not tick the "expert interviews" box unless you are actually doing expert interviews.</p> <p>Please ensure you have included a detailed description of any of the procedures or methods selected here in the procedures question 5.6.</p> <p>Click here for further information on these methods of data collection.</p>
<input type="checkbox"/> Action Research															
<input type="checkbox"/> Autobiography/Auto-Ethnography															
<input type="checkbox"/> Data Linkage															
<input type="checkbox"/> Deception															
<input type="checkbox"/> Ethnographic Fieldwork															
<input type="checkbox"/> Expert Interviews															
<input type="checkbox"/> Focus Groups															
<input type="checkbox"/> Naturalistic Observation															
<input type="checkbox"/> Random Digit Dialing															
<input type="checkbox"/> Secondary Use of Data															
<input type="checkbox"/> Subject Pools															
<input type="checkbox"/> Use of Medical Records															
<input type="checkbox"/> Videotaping															
<input type="checkbox"/> None of these Methods															

VIEW 6

6. PARTICIPANT INFORMATION AND CONSENT PROCESS - HUMAN ETHICS APPLICATION

* 6.1. Time to Participate

How much time will a participant be asked to dedicate to the project?

Include how many minutes/hours over how many weeks/months the participant will be asked to dedicate to the project. If your study involves no direct interaction with participants (e.g., naturalistic observation) you would respond "N/A".

Ensure that you also include this information in the consent process and that the amount of time stated is consistent in the application, recruitment letters or posters, and consent information.

6.2. Risks

Describe what is known about the risks of the proposed research for participants.

Include information about any physical, social, or psychological risks that the participants are likely to experience as a result of taking part in the study.

Click [here](#) for further information on risks.

6.3. Benefits

Describe any potential benefits to the participant that could arise from his or her participation in the proposed research.

Specify the benefits to the participants. If there are no benefits, state this explicitly. If any specific therapeutic benefits cannot be assured, but may be hoped for by the participant, state explicitly that the participant may or may not benefit from participation in the study.

6.4. Impacts on Community

If your research involves an identified group or 'community', outline the likely impacts of the research on the community.

Research involving identified groups often has impacts (both positive and negative) that go beyond individual participants.

The REB cautions against analyses that may contribute to stereotyping of groups

	<p>on the basis of ethnic or cultural background, sexual orientation, etc. Therefore, when the study includes specific groups or a range of groups and asks participants to categorize themselves according to ethnicity, colour, etc., the researcher must describe the nature of the analysis to be undertaken.</p> <p>If Aboriginal groups are the focus of analysis then the REB takes direction from chapter 9 of TCPS2.</p>
<p>6.5. Reimbursement</p> <p><i>Describe any reimbursement for expenses (e.g., meals, parking, medications) or payments/gifts-in-kind (e.g., honoraria, gifts, prizes, credits) to be offered to the participants. Provide full details of the amounts, payment schedules, and value of gifts-in-kind.</i></p> 	<p>In accordance with TCPS2, the REB takes a neutral stance on the use of incentives. However, "where incentives are offered to participants, they should not be so large or attractive as to encourage reckless disregard of risks... The offer of incentives in some contexts may be perceived by prospective participants as a way for them to gain favour or improve their situation. This may amount to undue inducement" (see TCPS2 Article 3.1).</p> <p>Click here for further information on reimbursement and payments.</p>
<p>6.6. Obtaining Consent</p> <p><i>Specify how potential participants will be invited to take part in the study. Include details of where the consent will be obtained and documented, and under what circumstances.</i></p> 	<p>Article 3.12 of TCPS2 states that "Evidence of consent shall be contained either in a signed consent form or in documentation by the researcher of another appropriate means of consent" (see also Article 10.2).</p> <p>Include the following details:</p> <ol style="list-style-type: none"> 1. Who would approach the participant to obtain consent. 2. Who would inform and take the consent from the participant. 3. What is the relationship of the person obtaining consent to the participant. <p>The REB recognizes that written consent is not necessarily appropriate for certain types of research. Researchers wishing to obtain oral consent should describe the alternative means of obtaining and documenting consent. A script of the oral consent process should be appended to question 9.2 of the application.</p>
<p>6.6.A. Waiver of Consent</p> <p><i>If you are asking for a waiver or an alteration of the requirement for</i></p>	<p>Conditions for waiver/alteration of consent:</p> <ol style="list-style-type: none"> 1) The research involves no more than

<p>participant informed consent please justify the waiver or alteration and confirm that the study meets the criteria on the right. Please address each criterion individually.</p> 	<p>minimal risk to participants; 2) The lack of consent is unlikely to adversely affect the welfare of the participant; 3) It is impossible or impracticable to carry out the research and to answer the research question properly without the waiver or alteration; 4) Whenever possible and appropriate, the participants will be debriefed and provided with additional pertinent information after participation; 5) The waived or altered consent does not involve a therapeutic intervention.</p>
<p>6.7. Time to Decide</p> <p>How long after being provided with detailed information about the study will the participant have to decide whether or not to participate? Provide your rationale for the amount of time given.</p> 	<p>TCPS2, Article 3.2 states, "For consent to be informed, prospective participants should have adequate time and opportunity to assimilate the information provided, pose any questions they may have and discuss and consider whether they will participate. The time required for this initial phase of the consent process will depend on such factors as the magnitude and probability of harms, the complexity of the information conveyed and the setting where the information is given".</p>
<p>* 6.8. Capacity to Consent</p> <p>Will every participant have the capacity to give fully informed consent on his/her own behalf? Please click "Select" to complete the question and view further details.</p> <p>Yes</p>	<p>Click here for information on individuals who lack the capacity either temporarily or permanently to consent for themselves.</p> <p>Please note that not having attained the legal age of majority in BC (19 years) does not necessarily mean that the participants are unable to provide their own consent.</p>
<p>6.9. Renewal of Consent</p> <p>Describe any situation in which the renewal of consent for this research might be appropriate, and how this would take place.</p> 	<p>TCPS2, Article 3.3 states, "In general, participation should be based on consent that is voluntary, informed, and ongoing throughout the duration of the research".</p> <p>Renewal of consent might be particularly appropriate in the context of longitudinal, ethnographic or other research methods involving multiple contacts with participants.</p>
<p>6.10. Provisions for Consent</p> <p>What provisions are planned for participants, or those consenting on a participant's behalf, to have special assistance, if needed, during the</p>	<p>Attach copies of contact letters or consent documents that have been translated into other languages to question 9.2 of the application.</p>

consent process (e.g., consent forms in Braille, or in languages other than English).

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6.11. Restrictions on Disclosure

Describe any restrictions regarding the disclosure of information to research participants (during or at the end of the study) that the funder/sponsor has placed on investigators, including those related to the publication of results.

An empty rectangular text box with a light beige background and a thin border. It features a vertical scrollbar on the right side and a horizontal scrollbar at the bottom, indicating it is a scrollable area for text input.

Click [here](#) for information on **UBC's Conflict of Interest policy**.

VIEW 7

7. NUMBER OF PARTICIPANTS AND LOCATIONS FOR BEHAVIOURAL STUDY - HUMAN ETHICS APPLICATION

* 7.1. External Approvals

External approvals for research involving other institutions and other jurisdictions: Provide written proof of agency approval for projects carried out at other institutions and, when applicable, other jurisdictions.

Indicate external approvals below:

A.

Other Institutions:

Yes No [Clear](#)

B.

Please select "Add" to enter the name of the institution and if you have already received approval attach the approval letter.

Name of Institution	Document(s)
There are no items to display	

* C.

Other Jurisdiction or Country (if answer is "No" go to 7.2):

Yes No [Clear](#)

D.

Please select "Add" to enter the name of the jurisdiction or country and if you have already received approval attach the approval letter.

Name of Jurisdiction or Country	Document(s)
There are no items to display	

E.

Has a Request for Ethics Approval been submitted to the institution or responsible authority in the other jurisdiction or country? (**Send a copy to the Research Ethics Office when approval is obtained**).

Yes No [Clear](#)

F.

If a Request for Approval has **not been** submitted, provide the reasons

7.1 A. External Approvals

Written evidence of approval (to use the premises or to access students, clients, patrons or patients) is required for projects carried out at other institutions. If agency approval cannot be obtained without prior approval of the UBC REB, a letter of conditional approval will be issued for submission to the institution if all other aspects of the application are satisfactory. Please indicate whether a request for approval has been submitted to the institution or whether conditional approval by the UBC REB must accompany a request to the institution for approval.

7.1 E Other Jurisdictions

TCPS2 [Article 8.3\(b\)](#) states, "Research conducted under the auspices of a Canadian research institution and conducted outside its jurisdiction... shall undergo prior ethics review by both: (i) the REB at the Canadian institution...; and (ii) the REB or other responsible review body or bodies, **if any**, at the host research site. Please indicate if any agencies have jurisdiction over the site of the research and whether approval has been applied for or received. If formal research ethics approval processes are not in place at the study site, explain this in 7.1 F.

7.1 G Research with aboriginal communities

Click [here](#) for TCPS2 Chapter 9 on Research Involving the First Nations, Inuit and Metis Peoples of Canada

Click [here](#) for CIHR Guidelines for Health Research Involving Aboriginal People

7.1 H Registration of Clinical Trials

If there is any possibility of the intent to publish the results of the study in an ICMJE (International Committee of Medical Journal Editors) member journal, and it falls under their definition of a clinical trial (which includes **behavioural treatments, dietary**

below:

G. Does this research focus on aboriginal peoples, communities or organizations?

Yes No [Clear](#)

If "Yes", ensure that you are familiar with the guidance documents linked on the right. Also attach a copy of the research agreement with the community (if available) in question 9.7. Please describe the community consent process. If no community consent is being sought, please justify.

H. Registration for Publication of Clinical Trials. Does this study fall within the clinical/intervention trial definition stated on the right (in the guidelines)?

Yes No [Clear](#)

If 'Yes', click 'Add' to enter the following information. (Please note that registration by UBC ORS administration requires the prior ethical approval of the study. In that case, registration information should be added when it becomes available).

Has it been registered?	Authorized Registry used	Clinical Trial unique identifier
There are no items to display		

interventions and process-of-care changes), the study must be registered BEFORE it is started (but not necessarily before ethical approval is granted). Please click [here](#) for further details.

7.2. Number of Participants

A.

How many participants will take part in the entire study (i.e., the entire study, world-wide)?

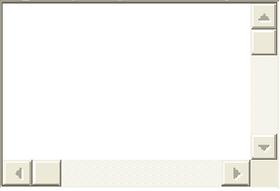
B.

Unless you are conducting a multi-sited study involving several institutions, the responses to A and B are likely to be the same.

How many participants will take part at institutions covered by this Research Ethics Approval (i.e., only at the institutions covered by this approval)?

*** 7.3. Researcher Qualifications**

Who will actually conduct the study and what are their qualifications to conduct this kind of research? (e.g., describe relevant training, experience, degrees, and/or courses).



VIEW 8

8. SECURITY OF DATA AND CONFIDENTIALITY OF PERSONAL INFORMATION FOR BEHAVIOURAL STUDY - HUMAN ETHICS APPLICATION

8.1. Security of Data During the Course of the Study

How will data be stored? (E.g., computerized files, hard copy, videotape, audio recordings, personal electronic communications device, other.)

How will security of the data be maintained? (For example, study documents must be kept in a secure locked location and computer files should be password protected and encrypted, data should not be stored or downloaded onto an unsecured computer, back up files should be stored appropriately.)

If any data or images are to be kept on the Web, what precautions have been taken to prevent them being copied?



Click [here](#) for further information on **Confidentiality**.

8.2. Access to Data

Who will have access to the data (e.g., co-investigators, students or translators)? How will all of those who have access to the data be made aware of their responsibilities concerning privacy and confidentiality issues?



Give the names (if known) of those who will have access to the raw data, which may include information that would identify the participants. The research participants must also be told in the consent process who will have access to his/her data and what use will be made of it, either now or in the future. Temporary student assistants, translators, transcriptionists and clerks may be referred to by their role instead of name.

8.3. Protection of Personal Information

Describe how the identity of research participants will be protected both during and after the research study, including how participants will be identified on data collection forms.



Click [here](#) for further information on protection of personal information.

Data linkage studies: If your study involves the linkage of several data sources, explain how confidentiality regarding the shared information will be preserved.

8.4. Transfer of Data

Will any data that identify individuals be transferred (available) to persons or agencies outside of the University?

Yes No [Clear](#)

If **YES**, describe in detail what identifiable information is released, to whom, how the data will be transferred, how and where it will be stored and what safeguards will be used to protect the identity of participants and the privacy of their data. Attach the data transfer agreement if applicable.



8.5. Retention and Destruction of Data

UBC policy requires that data be kept for at least 5 years **within a UBC facility**. If you intend to destroy the data at the end of the storage period describe how this will be done to ensure confidentiality (e.g., tapes should be demagnetized, paper copies shredded). **UBC has no explicit requirement for shredding of data at the end of this period and it may be kept indefinitely**. Please note that the responsibility for the security of the data rests with the Principal Investigator.



According to UBC Policy #85 on Scholarly Integrity, data should be stored for at least 5 years within a UBC facility, but may be retained for a longer period provided that they are stored securely.

In some cases, data are of such value that they should not be destroyed (e.g., oral history interviews). In these cases, please describe your plans to preserve this material. The consent process should outline these plans and describe how and when it may be appropriate for others to have access to this information.

8.6. Future Use of Data

Are there any plans for future use of either data or audio/video recordings? Provide details, including who will have access and for what purposes, below.

Describe any known future use of the data beyond the conclusion of this research project, and indicate whether participant consent will be obtained in the current consent procedure or the participant will be contacted later to obtain consent. Either possibility must be described in the consent process. If consent is to be obtained now, the future use of the data must be described in full to the participant and included with the current application. If consent for future use of the data is to be

obtained later, full details must be submitted to the BREB for review and approval before the research begins.

The BREB acknowledges that in the case of **ethnographic field notes** and interviews, researchers cannot be expected to know all the uses they plan to make of the data. Therefore, researchers should inform the peoples they are studying of the potential for future use of the data during the consent process.

8.7. Feedback to Participants

Are there any plans for feedback on the findings or results of the research to the participant? Provide details below.

TCPS2, [Chapter 4](#) on equitable distribution of research benefits states that participating individuals, groups and communities are informed of how to access the results of the research. Results of the research should be made available to them in a culturally appropriate and meaningful format, such as reports in plain language in addition to technical reports.

VIEW 9

9. DOCUMENTATION - HUMAN ETHICS APPLICATION

Please attach the documentation for the study. The Research Ethics Office will NOT check the content of each attachment and cannot change document names or dates.

INSTRUCTIONS

View the guidelines to the right of each section to see where the document should be attached. Documents will appear on the certificate of approval with the information that you enter when you attach the document. Please check that version dates, document names etc. are accurate and match those on the attached documents. Submit final versions only (i.e. not "drafts") except that blanks can be included for names and addresses in documents to be sent to specific individuals or organizations. Revisions required by the Board should be highlighted.

New Applications: Attach the documents to the applicable section (refer to guidelines on right)

Response to Proviso or Deferral or Changes Required by REBA:

If you are submitting a revised version of a document that is already attached; delete only the document that you are replacing and attach the revised version of the same document (Do NOT delete any of the other documents). You may add a new document but you must indicate in your response that you have added a new document for review.

Amendments:

If you are submitting a revised version of a document that is already attached; delete only the document that you are replacing and attach the revised version of the same document (Do NOT delete any of the other previously approved documents, those should remain in the application).

If you are submitting a new document that is being added to the study; simply attach it to the applicable section (leave all other previously approved documents in the application).

9.1. Research Proposal

Examples of types of proposals are listed on the right. Click "Add" to enter the required information and attach the documents.

Document Name	Version	Date	Document

- Grant application
- Dissertation proposal
- Research proposal

9.2. Documentation of Consent

Examples of types of consent documents are listed on the right. Click "Add" to enter the required information and attach the documents.

Document Name	Version	Date	Document
There are no items to display			

- Participant consent form
- Parent/guardian consent form
- Other consent forms
- Description of process for obtaining consent (e.g. oral consent script)
- Click [here](#) for more guidelines on behavioural informed consent forms

9.3. Documentation of Assent

Examples of types of assent documents are listed on the right. Click "Add" to enter the required information and attach the documents.

Document Name	Version	Date	Document
There are no items to display			

- Participant assent form
- Other assent forms (e.g. oral assent script)
- Click [here](#) for more information on assent for the Vancouver & Okanagan BREBs
- Click [here](#) for UBC C&W Research Ethics Board assent template

9.4. Advertisement to Recruit Participants

Examples are listed on the right. Click "Add" to enter the required information and attach the documents.

Document Name	Version	Date	Document
There are no items to display			

Advertisement to Recruit Participants

This includes any type of communication (e.g. flyer, radio/television script, poster, newspaper ad, internet message) that is directed to potential participants for the purpose of recruitment. The purpose of this documentation is to ensure that the recruitment measures are appropriate and not coercive.

Click [here](#) for **BCCA Research Ethics Board policies participant handouts and advertisements.**

Click [here](#) for **UBC C&W Research Ethics Board** policies on participant handouts and advertisements.

9.5. Questionnaire, Questionnaire Consent Cover Letter, Tests, Interview Scripts, etc.

Please click "Add" to enter the required information and attach the documents.

Document Name	Version	Date	Document
There are no items to display			

If the study is limited to a questionnaire that is completed by the participant, a consent cover letter may be used in lieu of a standard consent form, provided it includes essentially the same information as a consent form, plus a sentence that states that "**If the questionnaire is completed, it will be assumed that consent has been given**". If a study involves other procedures and a consent form, a covering letter is not required, unless the questionnaire is completed or sent to the participant at a later date.

If the questionnaire will be accessed

	online, details of the survey webhost should be provided in 9.7B.								
<p>9.6. Letter of Initial Contact</p> <p>Please click "Add" to enter the required information and attach the forms.</p> <table border="1" data-bbox="66 569 792 659"> <thead> <tr> <th>Document Name</th> <th>Version</th> <th>Date</th> <th>Document</th> </tr> </thead> <tbody> <tr> <td colspan="4">There are no items to display</td> </tr> </tbody> </table>	Document Name	Version	Date	Document	There are no items to display				<p>Letters of Initial Contact – This is the preferred method of recruitment when contact is initiated by the researcher rather than by the participant responding to an advertisement and includes email invitations, follow up emails, reminders, etc.</p> <p>Telephone contact form – Initial contact by telephone is discouraged by the BREB. Interviews may be conducted by telephone after making contact by mail/email and obtaining consent. For surveys where initial contact is made by random digit dialing, complete and attach appendix 4 "Telephone Contact Form".</p>
Document Name	Version	Date	Document						
There are no items to display									
<p>9.7. Other Documents</p> <p>A.</p> <p>Other documents: Examples of other types of documents are listed on the right. Click "Add" to enter the required information and attach the documents.</p> <table border="1" data-bbox="66 1010 792 1100"> <thead> <tr> <th>Document Name</th> <th>Version</th> <th>Date</th> <th>Document</th> </tr> </thead> <tbody> <tr> <td colspan="4">There are no items to display</td> </tr> </tbody> </table> <p>B.</p> <p>If a Web site is part of this study, enter the URL below. Since URL's may change over time or become non-existent, you must also attach a copy of the documentation contained on the web site to one of the sections above or provide an explanation.</p> <div data-bbox="66 1268 354 1461"> </div>	Document Name	Version	Date	Document	There are no items to display				<p>If applicable, please attach a transcript (the document must include a version date) of any CD, tape or audio file and send the hard copy to the Research Ethics Office.</p> <p>Other documents regularly required include the following:</p> <ul style="list-style-type: none"> • Deception form and written or verbal debriefing. Please click here to complete the form, then save and attach it to question 9.7 • Evidence of Agency approvals from other institutions <p>If this is an application using the streamlined process as indicated in Question 4.5, please append ALL relevant documentation from the other approving REB, including the application form, all correspondence from and to the approving REB, the proposal approved, the certificate of approval, the other REB approved informed consents, etc.</p>
Document Name	Version	Date	Document						
There are no items to display									

VIEW B – ONLY FILLED OUT IF YOU RESPOND ‘YES’ TO QUESTION 4.7

B. Creation of a Research Database - HUMAN ETHICS APPLICATION

<p>* B.1. <i>What is the scope and purpose of the database?</i></p> 	<p>E.g., to conduct educational research that produces insights into how teaching and learning might be improved.</p> <p>Some institutions may request that a Privacy Impact Assessment (PIA) be completed when creating a research database. Consult your institutional privacy office for more information.</p>
<p>* B.2. <i>What are the anticipated benefits of the database?</i></p> 	
<p>B.3. <i>Over what period of time will data be collected?</i></p> 	<p>Include a clear date range of the information that will be included in the database. If data will be collected indefinitely, clearly indicate that data will be collected indefinitely or until the participant withdraws, if applicable.</p>
<p>* B.4.A. Sources</p> <p><i>What information source(s) are you accessing?</i></p>	<p>For example, student records, program evaluation data, routinely collected classroom data, etc.</p>

*** B.4.B.**

Provide specific details about the source(s), i.e., including name of the database or type of records, location etc.

*** B.5. A. Confidentiality**

Are you collecting personally identifying information? [If not, skip to B.6.A.]

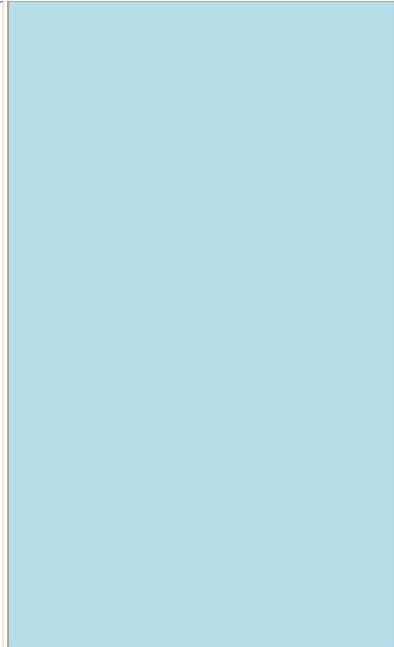
Yes No [Clear](#)

B.5.B.

Indicate the type of personally identifying information you will be collecting. Include a justification for its inclusion in the database.

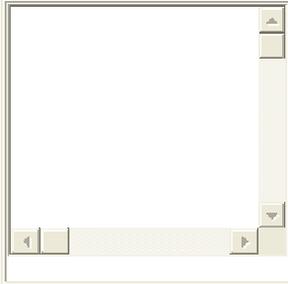
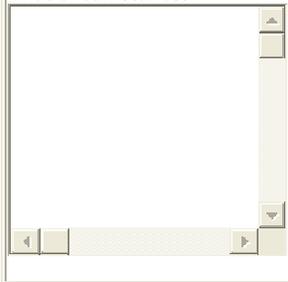
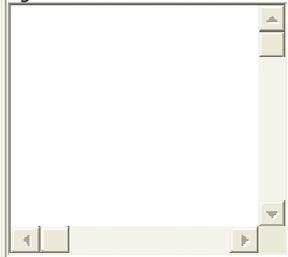
B.5.C.

How long will data remain identifiable (i.e., when, if ever, will it be irreversibly anonymized?). Explain why data needs to remain identifiable, if this is the case.

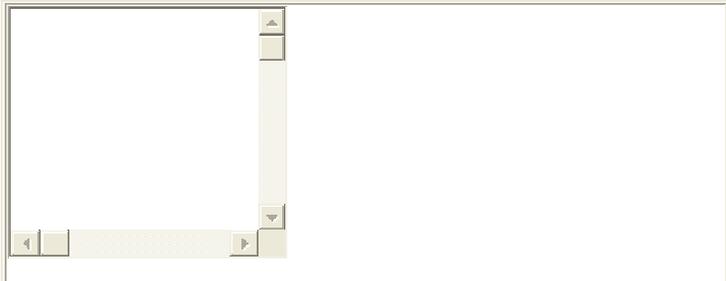
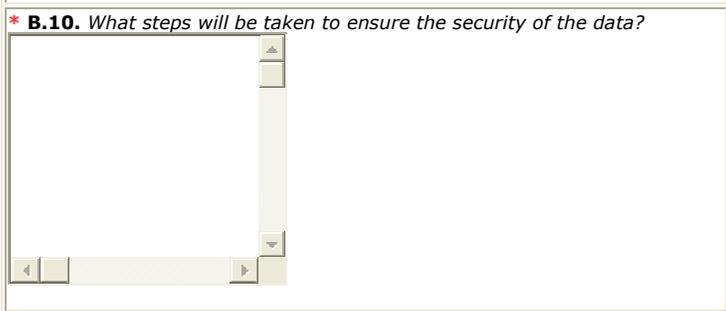
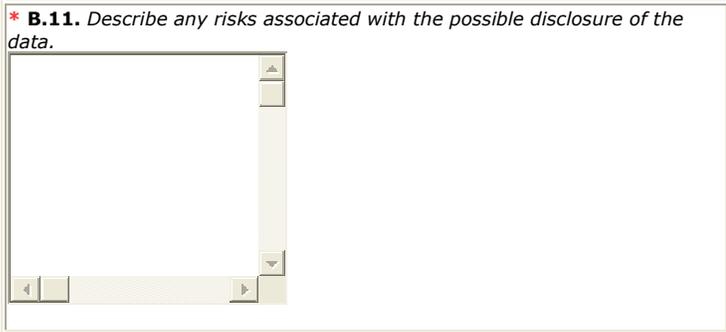


B.5.A. Personally identifying information is any information that may reasonably be expected to identify an individual, alone or in combination with other available information, e.g., name, SIN, student ID number, date of birth, address, or unique personal characteristic etc.

B.5.C. Irreversibly Anonymized data are irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low to very low.

	<p>Important Note: Attach a copy of the consent form to question 9.2. of the application.</p>
<p>* B.6.A. Consent</p> <p><i>Will participants consent to be included in the database and to have their data used for research purposes?</i></p> <p> <input checked="" type="radio"/> Yes <input type="radio"/> No Clear </p> <p>B.6.B.</p> <p><i>Specify who will explain the consent form and invite participants to contribute. Include details of where consent will be obtained and under what circumstances.</i></p> 	
<p>* B.7.</p> <p><i>If you do not plan to obtain individual participant informed consent, please provide justification for not doing so following the criteria outlined on the right. Please address each criterion individually.</i></p> 	

	<p>this research using this database exceeds the public interest in protecting the privacy of individuals;</p> <p>E. Demonstrate compliance with any known preferences previously expressed by individuals about any use of the information; and</p> <p>F. Confirm that any other necessary permission for secondary use of information for research purposes are in place.</p>
<p>* B.8.A. Participant access to data and withdrawal</p> <p><i>Will individual participants have the right to access their data, or right to amend or withdraw their information?</i></p> <p><input type="radio"/> Yes <input checked="" type="radio"/> No Clear</p> <p>B.8.B. <i>If you answered 'no', please provide a justification; if you answered 'yes' go to B.8.C:</i></p> <div data-bbox="66 905 354 1161" style="border: 1px solid #ccc; height: 122px; width: 177px;"></div> <p>B.8.C. <i>Provide details of the process for accessing and/or withdrawing data, including what data can be withdrawn.</i></p> <div data-bbox="66 1230 354 1486" style="border: 1px solid #ccc; height: 122px; width: 177px;"></div>	
<p>* B.9. <i>What is the entity or who is the person that will have custodianship of the database?</i></p>	<p>This is the person who is responsible for overseeing the management and use of the data, including the main rules governing use of the database, the process by which access requests will be reviewed, and the organization to whom the researcher is accountable for the</p>

	<p>proper management of the data.</p>
<p>* B.10. <i>What steps will be taken to ensure the security of the data?</i></p> 	<p>Reference procedural measures, technical measures, and physical measures planned for the protection of data. If a coding procedure is being used, describe the procedure in detail in this box.</p>
<p>* B.11. <i>Describe any risks associated with the possible disclosure of the data.</i></p> 	
<p>* B.12.A. Data Transfer</p> <p><i>Will data be sent outside of the institution? [If no, skip to B.13].</i></p> <p> <input type="radio"/> Yes <input checked="" type="radio"/> No Clear </p> <p>B.12.B.</p> <p><i>Explain why it is necessary to send the data outside of the institution, and indicate what data will be sent, where it will be sent, who it will be sent to, how it will be transferred (faxed, emailed, couriered, encrypted electronic transfer etc.) and where it will be stored.</i></p>	<p>Note that if this changes in the future an amendment must be submitted before data is transferred.</p>

B.12.C.

Will there be a data transfer agreement?

Yes No [Clear](#)

*** B.13.A. Data Linking**

Do you plan to link the data to any other databases? [If no, skip to B.14.A]

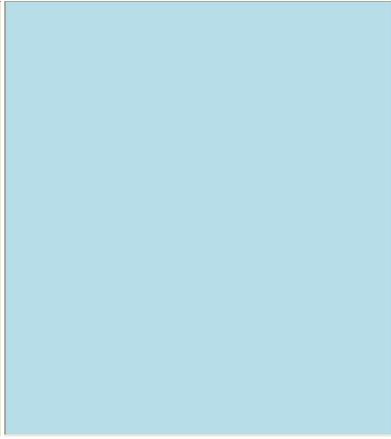
Yes No [Clear](#)

B.13.B.

Identify the data set, how the linkage will occur, and provide a list of data items in the other database. Also, identify what personal information will be used to link the databases and how confidentiality regarding this shared information will be preserved.

*** B.14.A. Data Retention**

How long are you planning to keep the data?



Note that if this changes in the future an amendment must be submitted before data are linked.



B.14.B.

If the data will be destroyed, indicate the planned method for erasure/destruction of the data.

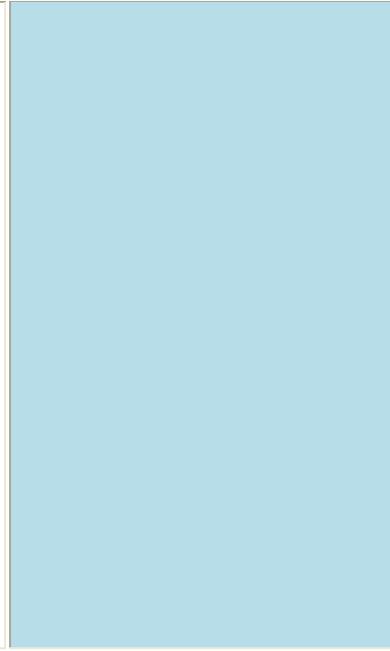
*** B.15.A. Future Use**

Will the information in the database be retained as an ongoing database (or as part of an ongoing database) for future research?

Yes No [Clear](#)

B.15.B.

Provide a full description of the data stewardship process.



B.15.B. Reference who will have access to the database in the future and under what circumstances, what will happen if an individual data custodian leaves the institution, where the ongoing database will be stored or maintained, and what security measures will be in place.

VIEW D – ONLY FILLED OUT IF YOU RESPOND 'YES' TO QUESTION 4.8

(THIS OPTION IS ONLY AVAILABLE FOR APPLICATIONS SUBMITTED TO THE UBC BEHAVIOURAL RESEARCH ETHICS BOARD AND UBC OKANAGAN BEHAVIOURAL RESEARCH ETHICS BOARD)

D. Class-based Projects - HUMAN ETHICS APPLICATION

* **D.1.** *If you selected medium vulnerability or medium research risk on the minimal risk matrix (see question 4.5.A), but the student project(s) still fall within the minimal risk category, please provide further information on how the additional risks will be mitigated and the experience of the students to deal with this.*

The BREB encourages instructors to ensure that student projects are conducted with low vulnerability populations and that the research itself involves a low level of risk, although exceptions that still fit within the minimal risk parameters are allowable. If the student projects will be low risk and with low vulnerability populations, please answer 'not applicable' to D.1.

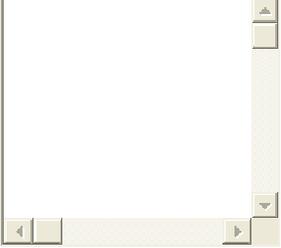
Important note: as the course instructor, final responsibility for the conduct of the student projects rests with you to ensure that the student projects meet the minimal risk criteria. If **any** of the student projects do not meet the minimal risk criteria (e.g., they involve a medium or high vulnerability population AND medium or high risk research), and you are willing to allow the project to proceed, a separate application for this project must be submitted to the BREB (using the normal BREB application form and channels), with the instructor as the PI and the student as the co-Investigator.

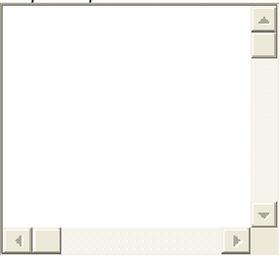
* **D.2.** *Describe the purpose of the assignment, e.g. to learn and practice research techniques.*

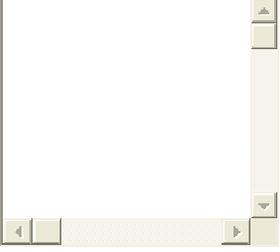
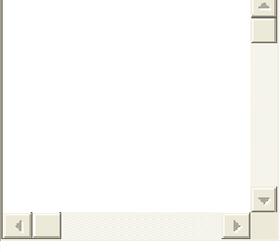
Please attach a course outline and any assignment materials to question 9.1 of the application.

D.3.A. *Describe the types of methods the students will be using in the class projects (e.g., surveys, participant observation, interviews, mixed-method*

If the students will potentially be using a range of methodologies, all should be

<p><i>studies, etc.) and general types of data students will be collecting.</i></p> 	<p>listed here.</p>
<p>D.3.B. Describe how will you ensure that the methodology described for the research will be followed by the students.</p> 	
<p>* D.4. What instructions will you be providing to students regarding recruitment?</p> 	<p>What types of recruitment methods will students be using in the course? Study advertisements? Direct approach? List the types of recruitment strategies students will use.</p>
<p>* D.5. What instructions will you be providing to students regarding obtaining consent from study participants?</p> 	<p>Please ensure that a template consent document is attached to question 9.2 of the application.</p>

<p>* D.6. <i>What instructions will you be providing to students on explaining participants' right to withdraw from the research project.</i></p> 	<p>This information should generally be outlined in consent documents.</p>
<p>* D.7. <i>What instructions will you be providing students regarding feedback for participants about the study (where applicable).</i></p> 	<p>For some types of student projects it may be appropriate to provide feedback to participants (e.g., if students are doing a mini-ethnography). Otherwise answer 'not applicable'.</p>
<p>* D.8. <i>What instructions will you be providing to students on assessing and minimizing risk to participants?</i></p> 	<p>Although the student projects will involve minimal risk, students should have an awareness of how any risks will be mitigated (e.g. confidentiality risks, potential for minor upset, etc.).</p>
<p>D.9. <i>Please describe how the subject of ethics in research involving human participants will be covered within the course.</i></p> 	<p>This might take the form of a lecture on ethics, assigned readings, class discussions, etc.</p>

<p>D.10. Please describe how you will ensure that students in the course have completed the TCPS tutorial.</p> 	<p>Students who are conducting research with human participants are expected to be familiar with the Tri Council Policy Statement and are required to complete the TCPS tutorial 'CORE'.</p>
<p>* D.11. Please describe how you, as course instructor, will review and approve the course projects proposed by your students, if they are not using the same standardized materials.</p> 	<p>This might take the form of a research proposal that students are required to submit, or individual meetings with the course instructor, etc.</p>
<p>D.12. Please explain how you intend to deal with the project materials (e.g. research proposals, signed consent forms, etc.).</p> 	<p>Please note that you are required to keep these materials for at least 6 months beyond the end of the semester, but they can be destroyed after this period.</p>
<p>D.13. Please confirm your acceptance of the following:</p> <p><input checked="" type="checkbox"/> I agree to comply with the requirements of the class-project guidelines and to ensure that the design of all student projects will fit within the criteria for these projects.</p> <p><input checked="" type="checkbox"/> I am familiar with and agree to abide by the ethical guidelines and policies of the Behavioural Research Ethics Board, including the Tri-Council Policy Statement and of my profession or discipline.</p>	<p>Please check each box to indicate your awareness of your responsibilities as the course convenor/instructor.</p>

<input checked="" type="checkbox"/>	I will actively monitor the progress of student projects and I will make myself available, should problems arise during the course of the research, to supervise the students and assist in solving such problems.	
<input checked="" type="checkbox"/>	If I have questions about the ethical conduct of this research I will contact the Behavioural Research Ethics Board.	
<input checked="" type="checkbox"/>	I agree to notify the BREB and my Department Ethics Officer (if applicable) of any unanticipated ethical problems encountered by the student investigators in the course of their research.	

VIEW F – ONLY FILLED OUT IF YOU RESPOND 'YES' TO QUESTION 4.6

(THIS VIEW IS ONLY AVAILABLE TO APPLICANTS SUBMITTING TO THE UBC BEHAVIOURAL RESEARCH ETHICS BOARD OR THE UBC OKANAGAN BEHAVIOURAL RESEARCH ETHICS BOARD)

F. Harmonized Review of Multi-Jurisdictional Studies - HUMAN ETHICS APPLICATION

* **F.1.** *Is this a minimal risk study that has been approved by another Canadian Research Ethics Board?*

Yes No [Clear](#)

Behavioural minimal risk studies that have been approved by another Canadian Research Ethics Board are eligible for delegated review at UBC, including submission of a truncated application. If you answer yes to this question, you will automatically be re-directed to view 9 and required to attach all relevant documentation, including all documents submitted to the other Canadian REB. The application and correspondence between the researcher and the REB **must be** attached in question 9.7.

Please note that minimal risk studies reviewed and approved by another Canadian REB are eligible for harmonized review, even if UBC has no reciprocity agreement in place with the institution that conducted the initial review. Also, if you respond "Yes" to F.1, then your responses to the following questions are not important, although theoretically your response to F.2 should be "No".

* **F.2.** *Is this the first/initial application for review of a multi-jurisdictional study at any of the sites where the research is going to be conducted?*

Yes No [Clear](#)

The **first/initial application for review** is the first application for ethical review of the research submitted to any of the Institutions with which UBC has a signed reciprocity agreement.

UBC has entered into partial reciprocity and collaborative review arrangements with certain other institutions and entities in situations where a study requires review and approval by more than one Canadian Research Ethics Board. For detailed guidance on harmonization processes and requirements click [here](#). For a list of

	institutions with which UBC has a reciprocity or collaborative review agreement click here .
<p>* F.3. Are you the Lead Investigator for this multi-jurisdictional study? (See definition on right)</p> <p><input type="radio"/> Yes <input checked="" type="radio"/> No Clear</p>	<p>The Lead Investigator is the only Investigator conducting the multi-jurisdictional study at various sites or the Investigator chosen from amongst numerous Investigators from various sites to lead the multi-jurisdictional study.</p> <p>The Lead Investigator is the Investigator who submits the first/initial application for ethical review of the multi-jurisdictional study at any of the sites where the research is going to be conducted. The Lead Investigator is required to submit the initial application for review of the research to his or her home institution's REB regardless of where the research is taking place.</p> <p>If this is an initial application for review of the study and you are NOT the lead investigator, you cannot continue with this submission.</p> <p>If you are a UBC faculty member, you cannot answer 'No' to question F.2 and 'Yes' to question F.3 because UBC must perform the review of initial/first application since UBC is your home institution.</p>
<p>Check the institution below</p> <p><input type="checkbox"/> Simon Fraser University</p> <p><input type="checkbox"/> University of Alberta</p> <p><input type="checkbox"/> University of Northern British Columbia</p> <p><input type="checkbox"/> University of Saskatchewan</p> <p><input type="checkbox"/> University of Victoria</p> <p><input type="checkbox"/> None of the above</p>	