UVic Instructions for the Provincial Research Ethics Platform (PREP) for Harmonized Ethics
Guidelines and Tips for UVic Researchers and Their Graduate Students

Ethics Harmonization in BC

From 2014, the following BC partner institutions harmonized their human ethics review and approval systems for studies that require ethics clearance from two or more of the partners’ research ethics boards:

<table>
<thead>
<tr>
<th>Academic Institutions</th>
<th>Health Authorities</th>
<th>UBC-affiliated Institutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>UBC &amp; UBC-Okanagan</td>
<td>Fraser Health</td>
<td>BC Cancer</td>
</tr>
<tr>
<td>UVic</td>
<td>Interior Health</td>
<td>Children &amp; Women’s Hospital</td>
</tr>
<tr>
<td>University of Northern BC</td>
<td>Island Health</td>
<td>Provincial Health Services Agency</td>
</tr>
<tr>
<td>Simon Fraser University</td>
<td>Northern Health</td>
<td>Vancouver Coastal Health</td>
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<tr>
<td>Thompson Rivers University</td>
<td>First Nations Health Authority</td>
<td></td>
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<tr>
<td>Langara College</td>
<td>Camosun College</td>
<td></td>
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<tr>
<td>BC Institute of Technology</td>
<td>Kwantlen Polytechnic University</td>
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</table>

Harmonization removes duplication in the ethics process, and reduces researchers’ efforts and time\(^1\) in any of the following cross-institutional scenarios:

- Research team members are distributed across institutions
- Researcher(s) conducts their activities (participant recruitment, data collection, human materials collection, data storage) at partner institution(s)
- Researcher(s) access student records, patient charts, human biological samples/materials etc. at partner institutions

The current harmonized system only applies in BC between the above partner institutions.\(^2\)

\(^1\) Research Ethics BC [www.researchethicsbc.ca](http://www.researchethicsbc.ca) or [www.bcethics.ca](http://www.bcethics.ca)

\(^2\) It is anticipated that more BC institutions will join in the near future.

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Harmonization is not limited to health and clinical research. It is open to humanities, social science, education, and all research involving human participants subject to the national research ethics policy (TCPS2) are eligible.

What is the Provincial Research Ethics Platform? (PREP) Is PREP different from UBC RISe?

The Provincial Research Ethics Platform (PREP) is a new 2018 iteration of the well-established UBC online research ethics system called “RISe.” (RISe = “Research Information Systems”)

In 2017-2018, RISe was upgraded to serve as the one-stop province-wide ethics platform for researchers when their study involves ethics clearance from two or more partner institutions. Hence RISe is known also by its provincial-wide functions as “PREP.” RISe and PREP refer to the same system.

When you are in the PREP System and in the log-in home page, remember that while you are using a system that is designed for harmonized studies, it was built chiefly for UBC researchers.

Meet You in the Provincial Research Ethics Platform (PREP)!

It may look different, but UVic Ethics staff will be there with you.

Common Questions from UVic Researchers

When a UVic researcher submits a study on PREP is the UVic Ethics Board involved in the review of my study?

- Yes, it is a requirement that we are involved. Remember that we, UVic is your home academic institution.

- When a UVic researcher submits a harmonized study, UVic Ethics will be involved in your process.

- UVic Ethics will be involved together with whichever partner ethics board(s) (BC health authority/authorities or universities) you identify in the ethics application form. This is the foundation of harmonization; a one stop process for you, the researcher.
For instance for one study it might be UVic + Island Health. For another study, it might be UVic + SFU + UBC. For a large province-wide health study it might be UVic + all the BC Health Authorities.

**Because the application is submitted to UBC’s system, does this mean that my application is automatically - and only - reviewed by the UBC Ethics Board?**

- No. Remember that we, UVic is your home academic institution. We have not “outsourced” ethics reviews to UBC. This would go against our own UVic research policies.

- We will always be involved in your process. As a harmonized study, there will be at least one other partner institution involved in your process together with UVic.

- UBC is providing UVic ethics (and all the partner institutions) with use of the system. That use is restricted ONLY to the reviewing and approval of harmonized studies.

**I’m worried because everything on the system, in the guidelines and the ethics application form itself is “UBC-centric.”**

- Please do not worry! As a UVic researcher who is conducting a harmonized study, you are a *visiting user of this system.*

  *It will feel a little strange at first, especially if harmonized reviews are new to you or you have only experienced UVic’s research ethics process or the majority of your own research never involves another research ethics board aside from just UVic’s.*

Please refer to the section of this document “**HOW TO ANSWER QUESTIONS IN THE PREP ETHICS APPLICATION FORM AS A UVIC RESEARCHER**”

**What do I do if the questions on the ethics application form don’t apply (or don’t seem to apply) to UVic.**

- Please do not worry! Please work with the UBC guidelines and materials as best as you can. The contents are very helpful and reflect research ethics best practices regardless of which partner ethics board(s) UVic is involved with for your study’s harmonized review and approval process.

- When completing an ethics application form on PREP, UVic ethics anticipates that UVic researchers will identify procedures and sections where UVic policies and requirements differ from those of UBC (e.g., completion of the TCPS2 CORE tutorial is not a current requirement for UVic researchers).

  When in doubt, please try to apply UVic policies and procedures where applicable *as best as you can.* The UVic ethics staff will work with you (before and during the review process)
to clarify what is required at any point in the process. Also, the results of the ethics review that you will receive will outline UVic-specific requirements and directions as needed.

Please refer to the section of this document “HOW TO ANSWER QUESTIONS IN THE PREP ETHICS APPLICATION FORM AS A UVIC RESEARCHER”

When do UVic researchers use PREP? Was there a deadline?

- UVic researchers began using PREP in November 2018 for their harmonized studies. Some started as early as July 2018 to pilot the process.

- Effective January 1, 2019, all UVic researchers must use PREP for new harmonized reviews.

When do UVic researchers use UVic’s ethics online system (UVic-RAIS) in lieu of PREP?

Regular **UVic studies** are submitted on UVic-RAIS. Regular means “non-harmonized” and when UVic is the only BC Research Ethics Board that must be involved.

- If UVic ethics receives a new harmonized ethics application on UVic-RAIS the researcher will be re-directed to submit the application to PREP. They will be guided and supported through the PREP process if PREP and harmonization are unfamiliar to them.

- If a UVic approved study began as “non-harmonized” and the researcher proposes to amend it such that the study will require harmonized review, please contact the UVic ethics office. Such situations will be addressed on a case-by-case basis with the partner institution and researcher.

How does UVic ethics (and partner BC ethics boards) know when a UVic researcher has submitted a harmonized ethics application in PREP?

When a UVic researcher (or your research colleague from a partner institution) completes specific fields in an ethics application in PREP, the study is flagged for harmonization when any of the following occur:

- team member(s) and graduate students are listed as being from partner institutions
- the sites and locations where different research activities will occur are selected from a list of partner institution(s) (e.g., university campuses, clinics, hospitals, affiliated health clinics)
- the application flags that more than one partner BC institution is involved in the study

-** Even when a researcher does not have knowledge about harmonization, ethics staff from all partner institutions are trained to flag studies that required a harmonized review.**
UVic ethics staff are regularly on the PREP system. We also receive automatic notifications from PREP and emails from our ethics colleagues from our partner institutions.

UVic ethics staff are trained as administrators on PREP, and have managed harmonized reviews since 2014. We work closely with the research ethics staff and boards of partner institutions. Contact us. ethics@uvic.ca 250-472-4545.

UVic Research Ethics Coordinator, Eugenie Lam is on the BC advisory for ethics harmonization. Eugenie can be reached at 250-472-5202. hrethics@uvic.ca

GETTING SET-UP AS A UVIC RESEARCHER

To access PREP, UVIC researchers with no current appointment at UBC must apply for two UBC accounts in the following order: Campus Wide Log-in account, RISe account.

1. **Apply for a UBC “Campus-wide log-in” (CWL) account**

   Non-UBC affiliated individuals will create a **basic CWL** account ("Basic Account" option must be selected in the "Validate Your Identity" page). The **CWL account** is always created by the user and they get to choose their own **user name and password** that they have access to immediately.

2. **Apply for a RISe account**

   The UBC RISe Support Staff will create a researcher RISe account for you. The RISe account is connected to a “RISe Profile” (with your coordinates).

   Email the following to UBC RISe support risesupport@ors.ubc.ca and request a RISe account:

   - *Title (e.g., Dr., Mr., Ms, etc.):*
   - *Full First name/Middle initial/Last name:*
   - *Work E-mail address:*
   - *Work Telephone number:*
   - *Rank:*
   - *Dept./UBC Affiliation:*
   - Main work location (if at hospital):
   - UBC Employee number (if available):

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If you are a UVic researcher (faculty, student, staff) with an active UBC affiliation (e.g., dual appointment with a UBC-affiliated hospital such as BC Cancer, Providence, Children & Women’s Hospital etc., or you are with Island Medical Program) you DO NOT need to re-apply for an additional UBC CWL.
• UBC Student number (if available):
• Your CWL username:
  *Indicate your rank as a 'Non-UBC Faculty' or 'Non-UBC Employee' where appropriate.

Need help when applying for RISe account? Contact UBC’s Snezana Milosevic snezana.milosevic@ubc.ca Let her know that you are a UVic researcher for PREP.

Consistent with UVic ethics policies and procedures, only UVic faculty are permitted to hold the designation “Principal Investigator (PI)” in new studies submitted to UVic ethics including PREP. Names of UVic students and staff are be identified by their university/institution in the Research Team Section of the PREP application. See section “Special Instructions for UVic Student Researchers and their Supervisors.”

When created, an email with special code is sent to the user's email account. That code and researcher number is required for the initial login to the system. After the initial login, only your CWL is needed to login to PREP (aka RISe!) going forward.

In your RISe account “Work Information (Appointments and Affiliations)”

Specifically, for UVic individuals, UBC asks that you add “University of Victoria” in section 1.b within your RISe profile and also section 2 under 'UBC' dept name.

Indicate your rank as a 'Non-UBC Faculty' or 'Non-UBC Employee' where appropriate.

3. Log-in to RISe

Go to RISe homepage https://www.rise.ubc.ca/

Log-in with your CWL user name and password.

4. Helpful resources on the UBC RISe homepage https://www.rise.ubc.ca/

  • Explore the RISe Sandbox. This section of RISe allows you to create a mock application to become familiar with the application process.
  
  • Review the appropriate tutorial(s) that are available on the RISe website. (Tutorials are publicly accessible. No RISe account needed.)
  
  • Read and download the extensive Guidance Notes that are available for each of the six UBC Research Ethics Boards

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UBC researchers use the RISe system exclusively. The posted guidelines are primarily written for UBC researchers.
● Make use of the Forms & Templates available on the homepage https://www.rise.ubc.ca/

● Take advantage of the built-in Guidance Notes in the PREP ethics applications when it comes time to prepare an application.

SUBMITTING APPLICATIONS TO PREP AS A UVIC RESEARCHER – TIPS TO KEEP CALM & CARRY ON

As PREP is hosted and managed by UBC, the majority of the posted ethics guidelines, materials, and policies and procedures on the RISe homepage are written for UBC researchers in mind (faculty, students, staff). As a UVic researcher, you are a visiting user to the system.

Please work with the UBC guidelines and materials as best as you can. The contents are very helpful and reflect research ethics best practices regardless of which partner ethics board(s) UVic is involved with for your study’s harmonized review and approval process.

When completing an ethics application form on PREP we anticipate that you will identify procedures and sections where UVic policies and requirements differ from those of UBC (e.g., a declaration of Conflict of Interest for UBC faculty).

When in doubt, please apply UVic policies and procedures where applicable as best as you can. The UVic ethics staff will work with you (before and during the review process) to clarify what is required at any point in the process. Also, the results of the ethics review that you will receive will outline UVic-specific requirements and directions as needed.

The following section highlights some key areas that UVic researchers should be aware of when submitting applications on PREP as the Principal Investigator (PI) and how to proceed/respond.

Electronic Sign-Off Procedures

The procedures and questions in the PREP ethics application forms default to a UBC Principal Researcher (PI). Electronic sign-off for ethics applications defaults to a UBC department chair, director or dean.

Do NOT choose a UBC department in the "Departmental Approval" page if you are not from UBC 😞. UVic signatories are not programmed into the system to provide electronic sign-off. In this case you must choose "Research Ethics Board" from the drop-down list.

You will still be able to submit your PREP application without the UBC electronic sign-off.
UVic Signatures Page for UVic PI

When the UVic ethics board is involved in your harmonized review and a UVic faculty is the PI, you will upload the UVic Signatures Page with your department chair and dean’s electronic email signatures or hard copy signatures.

See Appendix 1 of this document for the Signatures Page. PREP will allow you to print a copy of your ethics application to aid your chair and dean to know about your study when they sign-off.

Don’t worry if you forget about the Signatures Page. UVic Ethics will provide you with the UVic Signatures Page via email and instructions if we don’t see it uploaded it in PREP.

Cross Appointments and Affiliate Appointments with BC Partner Institutions

If your primary appointment is at UVic do NOT choose a UBC department to sign off.

The exception is Island Medical Program (IMP) faculty as they already use the system for UBC signatory sign-off.

HOW TO ANSWER QUESTIONS IN THE PREP ETHICS APPLICATION FORM AS A UVIC RESEARCHER

Choose Study Type in PREP - Behavioural Research or Clinical Research

Question 4.1 asks you to choose between two study types (Behavioural or Clinical). When you make a selection, the application will automatically branch off to either the Behavioural Application Form or the Clinical Application Form.

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.

Note from UVic: Behavioural projects may also involve those from education, human and social development, health, fine arts.

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 as a Clinical study.

You can preview both application forms from the RISE homepage https://www.rise.ubc.ca/
Please contact UVic ethics if you need guidance about study type.
Questions on Ethics Application Form with UVic-specific considerations. You may answer “N/A” when they do not apply to you at UVic. The question numbers below are from on the Behavioural Ethics Application Form.

Q 1.6 TCPS2 CORE Tutorial (Course on Research Ethics online tutorial)
Applies only to UVic Graduate Students for their Projects, Capstone Projects, Theses, Dissertations that require ethical review

Effective May 1, 2020 UVic graduate students are required to complete a national research tutorial as part of their human ethics process.
https://tcps2core.ca/welcome

You may upload the CORE Certificate as an attachment either at the time of submitting the ethics application before review, or with your research ethics revisions/changes as instructed by the ethics board’s review.

The Harmonized Research Ethics Approval Certificate will NOT be issued to you until the CORE Certificate has been provided.

As CORE is a new requirement, the UVic ethics office will advise you and your supervisor of what is needed and when.

The Course in Research Ethics (CORE) tutorial is an online course launched by the federal government’s research funding agencies in 2011.

Please see UVic Frequently Asked Questions – includes help to register online.

2.4 A Source of Funds

Select response “Funds at other institutions” and identify UVic when funding will be held by or transferred to you as a UVic PI or a UVic Co-I.

Q 2.6 & Q 3 “Conflict of interest page: if answer to 2.6 is yes.”

Conflict of Interest (COI) declarations are managed at UVic in faculty members’ department and not within the ethics review application process.

Page 11 Health Authorities

When researchers identify in their PREP application that a health authority and/or a clinic that is under a health authority is involved in their study, additional instructions and information from the specified health authority/authorities will appear.

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Informed Consent Forms in PREP Informed Consent Forms

Please use the UBC templates for informed consent forms and add the UVic Research Ethics contact information: ethics@uvic.ca  250-472-4545.

When a UVic researcher is involved in a harmonized study, consent forms normally include the name and contact information of the ethics board that is the lead board for the specific study (“board of record”). In some studies, the contact information for more than one ethics boards may be recommended.

When your study undergoes a harmonized review, you will be provided with instructions and feedback from the UVic Ethics Board about ethics contact information on informed consent forms.

SPECIAL INSTRUCTIONS FOR UVIC STUDENT RESEARCHERS AND THEIR SUPERVISORS FOR PREP

When a UVic student conducts research involving humans to fulfill a thesis, dissertation, project, capstone project or honors project only UVic faculty are permitted to hold the designation “Principal Investigator (PI)" in new studies when submitting for ethics clearance to UVic. The PI designation applies to UVic when using PREP and UVic-RAIS.

UVic faculty supervising a UVic student in a study requiring harmonized review will need to apply for a UBC-CWL and RISE access.

The names of UVic students (and UVic staff) will be identified according to their university/institution in Questions 1 to 1.6 of the PREP application “Principal Investigator & Study Team.”

UVic Principal Investigators Designation (from UVic RAIS website)

UVic student researchers and Post-doctoral Fellows are no longer be able to hold the title "Principal Investigator" (PI).

Only faculty will be able to hold the "Principal Investigator" designation.

Please add UVic student researchers and Post-doctoral Fellows conducting their own project, thesis, or dissertation [in Questions 1 to 1.6 3 of the PREP] ethics application.

In such cases the faculty supervisor with be the PI.

The designations are for administrative purposes and do not change anyone's role in the research.
As UVic sign off is not electronically programmed into the PREP System, signatures must be obtained on this form when the PI is a UVic faculty or when the PI is supervising a Principal Applicant who is a UVic Graduate Student.

Instructions
1. Fill in the Signature Page Form (it's a Word document) up to section D.
2. PI provides their *electronic or ink signature* and date (section D).
3. PI downloads a PDF of their PREP application form to email to their departmental signatory. *This allows the signatory to be aware of the study they are signing off.*
4. PI obtains the *electronic or ink signature* and sign-off date of their chair, director or dean (Section D)
5. Upload the completed Signature Page Form to your ethics application form as an appendix on PREP.

Contact the Research Ethics Office if you have questions. 250-472-4545 ethics@uvic.ca

A. Principal Investigator (Must be a UVic Faculty Member)

*If there is more than one Principal Investigator, provide their name(s) and contact information below in Section B, Other Investigator(s) & Research Team.*

Last Name: First Name:

Department/Faculty: UVic Email:

Title/Position: (Must have a UVic appointment)
- [ ] Faculty
- [ ] Adjunct or Sessional Faculty (Appointment start and end dates): __________________

B. Principal Applicant (Must be a registered student conducting the study for a UVic degree (if applicable)

Last Name: First Name:

Department/Faculty: UVic Email:

- [ ] Undergraduate
- [ ] Masters Student
- [ ] Doctoral Student
- [ ] Post Doctoral
C. **Project Information**

Project Title:

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D. **Agreement and Signatures**

**Principal Investigator/Student Supervisor affirm that:**

- *I have read the application and it is complete and accurate.*
- *The research will be conducted in accordance with the University of Victoria regulations, policies and procedures governing the ethical conduct of research involving human participants and all relevant sections of the TCPS 2.*
- *The conduct of the research will not commence until ethics approval has been granted.*
- *The researcher(s) will seek further HREB review if the research protocol is modified.*
- *Adequate supervision will be provided for students and/or staff.*

______________________________

Signature

______________________________

Print Name

______________________________

Date

**Chair, Director or Dean**

*(To be signed by the person to whom the PI, or student’s supervisor reports, and must not be the same person as the PI or student’s supervisor. The Research Ethics Office cannot accept applications with duplicate signatures)*

I affirm that adequate research infrastructure is available for the conduct and completion of this research.

______________________________

Signature

______________________________

Print Name

______________________________

Date