Faculty of Pharmaceutical Sciences
PERL Stream Research Ethics Vetting Guide

Section I

Background

The Faculty's Pharmacy Education Research and Leadership (PERL) stream is one of four core research themes committed to achieving the Faculty's research mandate. PERL's primary goals are to: 1) advance the quality of pharmacy education through scholarly teaching,[1] educational scholarship and the Scholarship of Teaching and Learning (SoTL)[2] , and; 2) be a leader in pharmacy education scholarship and research locally, nationally and internationally. PERL fosters a collegial and collaborative environment that supports the development and growth of emerging educational scholars as well as their projects and research interests. Through mentorship from established scholars, PERL members build their teaching practices, research skills and new research initiatives.

One of the critical steps in developing an educational research project is formal ethics review to ensure ethical practice and conduct. For PERL projects that involve human subjects, are not clinical in nature, do not involve invasive procedures, and may include interviews, observations, or the administration of questionnaires, surveys or tests, UBC's Behavioural Research Ethics Board (BREB) is responsible for ethics review. However, not all PERL projects may warrant a formal BREB application and review. In consultation with UBC's Office of Research Ethics and with input from UBC's Centre for Teaching, Learning and Technology this vetting guide is provided for PERL members as a reference to better understand the criteria for making decisions about whether or not a formal BREB application and review is required.

Definitions of "research" and "quality improvement/assurance"

One of the key issues in determining whether or not a BREB review is required is understanding the definitions of and distinctions between "research" and "quality improvement/assurance" projects. Under Canada's Tri-council Policy Statement (TCPS2) outlining the ethical conduct of research involving humans,[3] "research" is defined as "an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation"; that is, the creation of new knowledge in the area of interest. In contrast, "quality improvement/assurance" is defined as projects that are "… exclusively for assessment, evaluation, management or improvement purposes" or the on-going quality improvement of teaching practices, courses and programs. Projects deemed "research" require formal ethics review while "quality improvement/assurance" studies do not.

Although the TCPS definitions may appear clear, uncertainty and confusion can still arise regarding the classification of educational scholarship and SoTL projects as research or quality improvement/assurance. Delineation requires, among other considerations, thinking carefully about the intentions or main purpose of the project and the final outcomes. For example, if the primary intent or purpose of the project is for on-going continuous quality improvement (CQI) of academic programs, courses and teaching practices, then it can be considered a quality improvement/assurance activity. These types of projects typically initiate immediate changes or tweaks to improve course design, teaching practices and programs based on project findings; the focus is generally on existing courses and programs, and within normal classroom/program practices, time and expectations. Studies that use routinely collected data as part of established program evaluation policy and/or efforts (e.g., Faculty-mandated course evaluation survey data or faculty member-initiated evaluation surveys and activities) represent the type of CQI activities exempt from formal BREB review. On the other hand, a

related project may have a similar purpose (i.e., to improve teaching practices, courses and/or programs), but requires additional knowledge and understanding before educational improvements can be made. These projects typically include measures, methods and data beyond the scope of normal classroom/program evaluation classroom practices, time and expectations, and findings that do not result in immediate changes to existing practices. Projects with this focus and that lay the foundation for subsequent educational changes and future CQI studies, would be considered research and require BREB review. Other educational projects considered research would be comparative studies of similar courses and teaching practices between different programs and/or institutions or have the objective to offer generalizable[4] commentary on similar programs. The key feature of these research projects is that the focus is beyond the boundaries of normal classroom/program evaluation practices. The table below provides additional criteria to help delineation between TCPS2 definitions of quality improvement/assurance and research.

Study criteria	Quality improvement/assurance	Research
Primary intent or purpose	Continuous quality improvement of teaching practices, courses and programs; immediate improvement of teaching and learning practices; purposeful educational change through scholarly teaching; fulfilling program evaluation requirements	Add to an existing body of scholarly literature; uncovering or creating new knowledge through the Scholarship of Teaching and Learning; dissemination to a larger audience; associated with a line of inquiry as opposed to "one off" studies
Context and locus of attention	Confined to existing courses and programs; scope limited to current curriculum and pedagogical practices; development of "best practices" in a narrow context	Beyond immediate classroom practices and requirements; improvements to curriculum and pedagogical practices often a longer-term goal; focused on greater understanding
Data sources	Faculty-mandated program evaluation surveys; faculty member-initiated evaluation surveys and activities; can include analysis of aggregate data and comparisons across years	Variable and often beyond regularly collected data as part of normal evaluation practices; data collection driven by the research questions asked
Expectations from faculty and of students	Data collection aimed at quality improvements and within normal classroom practice, time and expectations; reasons for data collection and changes made communicated directly to students	Often goes beyond normal classroom practice, time and expectations; reasons for data collection and study findings/ changes made communicated directly to students and/or study participants
Theoretical framework or lens[5]	Not always present and/or articulated in studies reporting or publishing "What was done?"; theories included focus on understanding impacts of	Important aspect of study design; helps organize study, in particular, analysis and interpretation of data; integrated in write-ups; improves credibility of findings; particularly important for studies answering

	curriculum design and improving teaching and learning practices	"Did it work?" and "Why or how did it work?" questions.
Generalizability (transferability)[4]	Often limited due to small numbers of study participants and the context-specific nature of the inquiries; addressed by providing descriptive details in reports and/or publications	A key focus; often limited due to small numbers of study participants and the context-specific nature of the inquiries; addressed by providing descriptive details in reports and/or publications. Alternatively, a broader participant population may be used beyond local contexts to increase numbers and make the study more generalizable.
Dissemination	Not always a key goal but can be disseminated locally, nationally and internationally at conferences and in written peer-reviewed publications	Typically a driving goal targeting local, national and international conferences and peer-reviewed publications

PERL members, as educators and developing educational scholars, are encouraged to think of the intellectual work of teaching as their form of scholarship and the scholarly activity generated from that work as research. In addition, while the TCPS2 definitions help classify research activities and provide guidance regarding requirements for formal BREB review, delineation of your project in no way impacts your ability to disseminate the work in public and peer-reviewed contexts through presentations, posters and written publications. What is important for dissemination purposes is acknowledging the work as research or a quality improvement/assurance activity as defined by the TCPS2. The former requires the BREB certificate approval number obtained as part of the formal ethics review process while the latter can be recognized by including specific language provided by UBC's Office of Research Ethics acknowledging Article 2.5 from the TCPS2 which states that, "quality improvement/assurance activities are not subject to institutional ethical review."

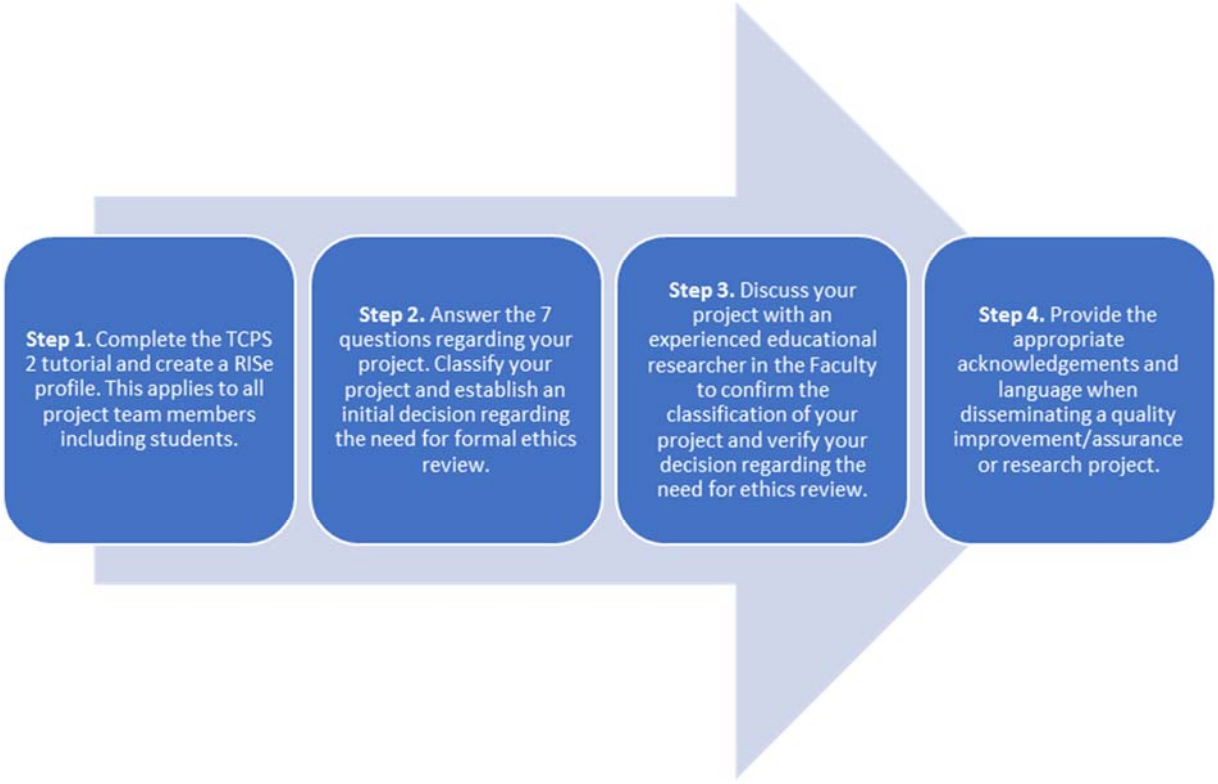
Section II

Ethical research practices

Regardless of whether formal BREB review is needed or not, there are expectations that educational research of all types will address adequate standards of ethical practice. Appendix I provides a set of ethical principles that should be incorporated into any form of research or quality assurance/improvement activity undertaken by PERL members. These ethical principles are central components of the TCPS2 tutorials that PERL members are encouraged to complete as part of the ethics vetting process described below.

Section III

Ethics vetting process (4 Steps)



To help classify educational scholarship and SoTL projects as research or quality improvement/assurance activities and to help determine whether or not a formal BREB application and review are required, PERL members and their research teams are asked to follow the steps below. The above diagram summarizes the process and Appendix 2 provides some examples of projects/studies that did and did not require formal BREB applications and review.

Step 1: Complete the TCPS 2 tutorial and create a RISe profile through the UBC RISe website.

The TCPS 2 tutorial is a self-paced, interactive online course that provides the foundations of research ethics review. The TCPS2 and related policies were created to ensure that ethical conduct of research involving human subjects in Canada is conducted to the highest standards. Find the TCPS 2 tutorial at http://www.pre.ethics.gc.ca/eng/education_tutorial-didacticiel.html; register for a RISe profile at https://www.rise.ubc.ca/accessing-rise. Step 1 should completed by all project team members including students.

Step 2: Answer the following 7 questions regarding your project and research questions. Questions 2-7 require "yes" or "no" answers. PERL members are encouraged to develop defensible answers that justify their responses:

1. Does the project/study fit the TCPS' definition of "research" or "quality assurance/improvement"? Explain.
2. Will any of the concepts of consent, informing students, confidentiality, vulnerability and beneficence be compromised at any time during the project?

3. Is there uncertainty of possible risk to any participant through experiencing either physical or psychological distress or discomfort?
4. Is the project design and methodology rigorous enough to statistically support generalizations beyond the particular context and/or population that will participate in the project?
5. Is the project funded by (or being submitted to) a grant/award competition from a funding agency that requires research ethics review?
6. Does the project involve "randomization" to contrast interventions to participants or other systematic sampling techniques to divide participants into different groups?
7. Does the project involve a comparison of interventions or processes and "control" settings or groups either to test a new intervention or to assess the effectiveness of a process change?

Decision point: If you are clear about your answer to question 1 and answered "No" to questions 2-7 then your project is likely a quality assurance/improvement project/study and may not require formal BREB review. If you are unsure about your answer to question 1 and/or answered "Yes" to any of questions 2-7 then your project may require a formal BREB application and review.

Step 3: To clarify the classification of your project and verify whether a formal BREB review is required, PERL members are encouraged to discuss their projects with an experienced educational researcher in the Faculty (e.g., Dr. Simon Albon, PERL Lead). If you need help crafting a formal ethics application, we have PERL members that can help facilitate the process. Contacting the UBC Office of Research Ethics directly for further verification may also be necessary (https://ethics.research.ubc.ca/about-human-research-ethics/contact-us).

Step 4: For your dissemination activities include the BREB approval certificate number for research projects and the following language (or variation of) for quality improvement/assurance projects, "Under Article 2.5 of Canada's Tri-Council Policy Statement governing research involving human subjects this project has been deemed a quality improvement/assurance activity and therefore not subject to institutional ethical review."

Footnotes

[1] **Scholarly Teaching (ST)**: goes beyond content knowledge and preparing and delivering a teaching session to observing a teaching-learning problem or opportunity, consulting literature, selecting and applying an educational intervention, conducting systematic observation, documenting observations, analyzing results and obtaining peer evaluation. The intent of scholarly teaching is to improve teaching practice and student learning (Medina et al, 2012; Richlin, 2001).

[2] **The Scholarship of Teaching and Learning (SoTL)**: builds on the end product of ST to include making teaching strategies and learning outcomes peer-reviewed and publically disseminated in appropriate media and venues. It involves identifying key issues from the process of scholarly teaching, analyzing results and putting them into the context of the existing knowledge base so others can comment and build on those efforts (Medina et al, 2012; Richlin, 2001).

[3] **The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans** (TCPS) is a joint policy of Canada's three federal research agencies: the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC). This Policy expresses the agencies' continuing commitment to the people of Canada to promote the ethical conduct of research involving humans. It has been informed, in part, by leading international ethics norms, all of which may help, in some measure, to guide Canadian researchers, in Canada and abroad, in the conduct of research involving humans.

[4] **Generalizability:** the degree to which study findings and conclusions from one context or population apply to other contexts or the population at large. For example, to what degree can we say that findings from educational studies at UBC's Faculty of Pharmaceutical Sciences apply to the other nine Canadian schools of pharmacy? Educational studies (both quality improvement/assurance and research) often have limited generalizability due to small numbers of study participants and the context-specific nature of the inquiries. Generalizability is addressed by providing enough descriptive detail in the reports and/or publications to allow readers to make connections between elements of a study and their own context and experiences. This process is referred to as **transferability**. (Gay, Mills & Airasian, 2009)

[5]The questions cited here were taken from a 2008 Medical Education paper proposing a framework for classifying the purposes of medical education research. (Cook, Bordage & Schmidt, 2008)

References

Cook DA, Bordage G, Schmidt HG. Description, justification and clarification: A framework for classifying the purposes of research in medical education. *Med Educ*. 2008;42(2):128-133. doi:10.1111/j.1365-2923.2007.02974.x.

Gay, L. R., Mills, G. E., & Airasian, P. *Educational research: Competencies for analysis and applications* (9th ed.). Upper Saddle River, NJ: Pearson Merrill; 2009.

Medina, MS, Bouldin, AS, Gonyeau M, Kissack, JC, Maldonado, WT, Melchert, RB, Moukhachen, O, Plaza, CM. Report of the 2011-2012 Academic Affairs Standing Committee: The evolving role of scholarly teaching in teaching excellence for current and future faculty. *American Journal of Pharmaceutical Education* 2012; 76(6): Article S5.

Richlin L. Scholarly Teaching and the Scholarship of Teaching. *New Dir Teach Learn*. 2001; (86):57- 68. doi:10.1002/tl.16.

Section IV

APPENDIX I

The following ethical principles apply to any form of research or quality assurance/improvement activity undertaken by PERL members that involving humans:

Consent

Participants should engage in studies only if they do so self-willingly. External factors that can influence or pressure the decision to participate must be avoided. Participants are respected as independent individuals and have the right to refuse or discontinue a project at any time.

Informing students

Regarding consent, participants must sufficiently understand the project details before engaging in it; they should be given sufficient time and opportunity to familiarize themselves with the study and ask questions about it. Study participants should not be intentionally misguided in anyway during the project and possible risks and benefits to study participants should be clearly explained. As new information emerges from a study, participants should be informed and maintain the right to withdraw at any time.

Confidentiality/anonymity/not divulging personal info

Information gathered from study participants should be collected in a form that secures their identity. Any identifying information must only be accessible by authorized personnel and cannot be disclosed/linked to external sources (without permission) or modified. A security strategy should be established to assure safe data collection, storage and destruction.

Vulnerability

Power differentials between faculty members (the researcher) and students can be problematic in educational research projects. In certain circumstances, students may feel the faculty member has leverage on their academic performance and profile. Minimizing this form of vulnerability in study design will improve the integrity of genuine consent.

Beneficence

Risk of harm (whether physical or mental) should be minimized for participants while the benefits of participation should be clearly communicated.

APPENDIX 2

Example I: A quality assurance/improvement project

Project/study title: Lecture capture in pharmacy education at UBC: Has anything changed?

Project overview: this project/study was a follow-up to the original lecture capture (LC) study published in 2014. The study was completed as a summer student research project. The purpose was to determine, approximately 8 years on, if student usage and faculty perceptions had changed. Three research questions guided the study: **1)** Have the patterns of students' usage of lecture recordings changed?; **2)** What is the current perceived value of lecture recordings to students and faculty members?, and; **3)** What is the effect of lecture recordings, if any, on student attendance?

Project team: S. Albon, K. Larson (PharmD student), JP Marchand

Answers to 7 questions:

1. **Does the project/study fit the TCPS' definition of "research" or "quality assurance/improvement"? Explain.**

   This project was classified as a quality assurance/improvement study. *In lieu* of an ethics vetting process discussions with UBC's Office of Research Ethics (ORE) confirmed this decision. **Primary intent:** fulfilling program evaluation requirements; **Context and locus of attention:** scope limited to the PharmD program, context narrow; **Data sources:** established LC surveys previously deployed to students and faculty; **Expectations from faculty and of students:** data collection aimed at greater understanding and quality improvements; within normal classroom practices and student and faculty expectations; **Theoretical framework or lens:** tangential although Mayer's principle of segmented learning provided direction on student learning with technology; **Generalizability (transferability):** limited and addressed by providing details in the publication, and; **Dissemination:** presented at UBC's MURC and as a peer reviewed publication (*Currents*; under review).

2. **Will any of the concepts of consent, informing students, confidentiality, vulnerability and beneficence be compromised at any time during the project?**

No; even though formal ethics review was not required we followed ethical practices of research involving humans.

3. **Is there uncertainty of possible risk to any participant through experiencing either physical or psychological distress or discomfort?**

   No; the data collection practices were familiar to students and faculty; the study was low risk.

4. **Is the project design and methodology rigorous enough to statistically support generalizations beyond the particular context and/or population that will participate in the project?**

   No; this project/study was narrowly focused on the PharmD program; there was no expectation that the results would be generalizable; generalizability was addressed by providing descriptive details in the publication.

5. **Is the project funded by (or being submitted to) a grant/award competition from a funding agency that requires research ethics review?**

   No; funding for the SSRP project was part of the OESD budget.

6. **Does the project involve "randomization" to contrast interventions to participants or other systematic sampling techniques to divide participants into different groups?**

   No; the study design did not include randomization.

7. **Does the project involve a comparison of interventions or processes and "control" settings or groups either to test a new intervention or to assess the effectiveness of a process change?**

   No; control groups were not used in the study design.

Ethics decision: Based on the project/study criteria and discussions with ORE this study did not require formal BREB application and review.

Wording used in posters and publications: "Following detailed discussions with the UBC Ethics Board, the project was deemed to be a quality assurance/quality improvement study and therefore not subject to formal institutional ethical review. Regardless, we followed the same protocol as for an ethics-approved study (ie, requesting consent and respecting confidentiality and anonymity)."

Example II: A research project

Project/study title: Exploring student perceptions of the learning environment in four health professions education programs.

Project overview: This pilot study examined the learning environment across four health professions programs at UBC (medicine, nursing, occupational therapy and pharmaceutical sciences) using the Health Education Learning Environment Survey (HELES) originally developed for medical students. The purpose was to assess the reliability of the measure across the four programs and explore similarities and differences in student perceptions of the programs. The findings, based on student-generated strengths and weaknesses, provided suggestions for enabling more positive learning environments within each program and promoting interprofessional collaborations regarding program improvements.

Project team: S. Rusticus (Medicine), D. Wilson (Medicine), Tal Jarus (Occupational Therapy), K. O'Flynn-Magee (Nursing), S. Albon (Pharmaceutical Sciences)

Answers to 7 questions:

1. **Does the project/study fit the TCPS' definition of "research" or "quality assurance/improvement"? Explain.**

   Primary intent: creating new and extending existing knowledge; adding to a growing body of scholarly literature; building a line of inquiry; new knowledge for the PharmD program and the Faculty; **Context and locus of attention:** beyond immediate classroom practices and requirements; involvement of multiple programs and learning contexts; improvements to curriculum and pedagogical practices a longer-term goal; **Data sources:** HELES previously deployed to medical students only; new data collection tool for pharmaceutical sciences; **Expectations from faculty and of students:** data collection beyond normal or regular Faculty/classroom evaluation practices; **Theoretical framework or lens:** Moos's learning environment framework used to create the HELES, organize the study, and an integral component of dissemination activities; **Generalizability (transferability):** applicable across four health professions programs; scope beyond pharmaceutical sciences, and; **Dissemination:** presented at CHES's Celebration of Scholarship event (2018), 24th European Network of Occupational Therapy in Higher Education Conference (2018), and as a peer reviewed publication (*Evaluation and the Health Professions*; under review).

2. **Will any of the concepts of consent, informing students, confidentiality, vulnerability and beneficence be compromised at any time during the project?**

   No; we followed ethical practices of research involving humans.

3. **Is there uncertainty of possible risk to any participant through experiencing either physical or psychological distress or discomfort?**

   No; although the HELES was new for our Faculty the data collection practices were familiar to students; low risk study.

4. **Is the project design and methodology rigorous enough to statistically support generalizations beyond the particular context and/or population that will participate in the project?**

   Yes; this project/study included multiple health professions programs and learning contexts; there was an expectation that the results would be generalizable supported by extensive statistical analysis.

5. **Is the project funded by (or being submitted to) a grant/award competition from a funding agency that requires research ethics review?**

   No; no funding was required for this study (except in-kind contributions of the collaborators).

6. **Does the project involve "randomization" to contrast interventions to participants or other systematic sampling techniques to divide participants into different groups?**

   No; the study design did not include randomization.

7. **Does the project involve a comparison of interventions or processes and "control" settings or groups either to test a new intervention or to assess the effectiveness of a process change?**

   No; control groups were not used in the study design.

Ethics decision: Based on the project/study criteria this study was deemed research and required formal BREB application and review.

Wording used in posters and publications: "After receiving ethical approval, each of the four health profession programs administered the HELES separately within their programs…"

Note about wording: as can be seen, minimal wording was included in the publication regarding the ethics approval process. If reviewers require additional information, the ethics certificate number will be included in revisions.

Example III: A research project

Project/study title: Exploring factors that influence student engagement in community-engaged learning activities within a pharmacy context (ExCEL-Rx).

Project overview: This project aims to investigate and identify factors that engage and motivate students to participate in community engaged learning activities. Taking a phenomenological approach, through in-depth semi-structured interviews with key stakeholders, we will compare and contrast motivating factors in community engaged learning between voluntary student-initiated community outreach initiatives and mandatory curricular service learning placements occurring within the Entry-to-Practice PharmD Program at UBC. We hope to leverage the information gathered to formulate strategies for improving student engagement in mandatory curricular service learning course(s) with potential application to other mandatory pharmacy experiential courses in the Entry-to-Practice PharmD Program.

Project team: K. Fang, G. Lau, P. Tchen, J. Park (PharmD student)

Answers to 7 questions:

1. **Does the project/study fit the TCPS' definition of "research" or "quality assurance/improvement"? Explain.**

   Primary intent: Creating new and extending existing knowledge on student engagement within a pharmacy context in community-engaged learning activities; continuous quality improvement of courses in the E2P PharmD Program involving community-engaged learning through findings. **Context and locus of attention:** Beyond immediate classroom practices and requirements; focused on greater understanding on student engagement; scope extends beyond the current curriculum to non-curricular voluntary community-engaged activities within a pharmacy context. **Data sources:** Interviews conducted with UBC pharmacy students that are beyond regular Faculty/classroom evaluation practices. **Expectations from faculty and of students:** Time expectations for data collection are beyond normal practice. **Generalizability (transferability):** Some concepts may be applicable more broadly, but findings are mostly limited to pharmacy education context. **Dissemination:** Publication is an overarching goal of the project.

2. **Will any of the concepts of consent, informing students, confidentiality, vulnerability and beneficence be compromised at any time during the project?**

   No; we followed ethical practices of research involving humans.

3. **Is there uncertainty of possible risk to any participant through experiencing either physical or psychological distress or discomfort?**

   No; data collection practices were familiar to students and faculty; the study was low risk.

4. **Is the project design and methodology rigorous enough to statistically support generalizations beyond the particular context and/or population that will participate in the project?**

   While certain results regarding student engagement may have some generalizability, findings are mostly limited to a pharmacy education context. Our low sample size also limits generalizability.

5. **Is the project funded by (or being submitted to) a grant/award competition from a funding agency that requires research ethics review?**

   Funding was provided based on a submitted proposal to the UBC Centre for Community Engaged Learning (CCEL), but research ethics review was not mandated.

6. **Does the project involve "randomization" to contrast interventions to participants or other systematic sampling techniques to divide participants into different groups?**

   No, the project did not incorporate randomization in such a manner.

7. **Does the project involve a comparison of interventions or processes and "control" settings or groups either to test a new intervention or to assess the effectiveness of a process change?**

   No, control groups were not used in the study design.

Ethics decision: Based on the project/study criteria, this study was deemed research and a BREB application was submitted and approved.

Wording used in posters and publications: TBD; project still in progress.