

Research Ethics Board

2022/2023 Annual Report

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&

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INTRODUCTION

This year saw the launch of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022)*, which replaces the TCPS 2 (2018). Four key areas that were updated in this latest version of the TCPS are:

- Broad consent for the storage of data and human biological materials for future unspecified research (Chapters 3 and 12). These changes are important for many researchers at KPU, since it outlines how to ensure the retention of data and human biological materials for future unspecified research is consistent with the TCPS.
- Streamlining multi-jurisdictional research ethics review of minimal risk research (Chapter 8). The KPU REB has been a part of the BC harmonization process since 2020.
- Research involving totipotent stem cells (Chapter 12).
- Review of research involving human cell lines (Chapter 12)

See a summary of the changes on the Panel on Research Ethics website:

https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022_changes-modifications.html¹

The REB Chair and Coordinator undergo continuous training and are responsible for keeping updated on Panel on Research Interpretations, updates involving the BC harmonization process, and emerging issues. This year's central emerging issue and related training was data security and privacy. This report provides details on the number of ethics applications reviewed, as well as highlights of a number of REB activities, including policy development and outreach.

Research Ethics Board Policy and Procedure

The REB has a distinct function and is governed by specific agreements. KPU has signed the *Agreement on the Administration of Agency Grants and Awards by Research Institutions* and as such the REB is mandated to follow and implement the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS 2). The REB's mission and mandate are governed by internal policies and procedures (e.g., [RS1: Research Involving Human Participants](#)) and relevant external policies, laws, and ethical frameworks.

The Research Ethics Process and Risk Assessment

One of the three guiding principles of the TCPS 2 is Concern for Welfare, which “means that researchers and REBs should aim to protect the welfare of participants, and, in some circumstances, to promote that welfare in view of any foreseeable risks associated with the research” (p. 7). The TCPS 2 outlines how research ethics boards are to make decisions regarding risks and mitigation.

¹ https://ethics.gc.ca/eng/tcps2-eptc2_2022_introducing-presentation.html

“Harm is anything that has a negative effect on the welfare of participants, and the nature of the harm may be social, behavioural, psychological, physical or economic. A proper ethical analysis of research should consider both the foreseeable risk and the available methods of eliminating or mitigating the risk” (p. 21).

Each REB application is assessed for risk in a number of ways including an evaluation of minimal risk. **Minimal risk research** is defined in the TCPS 2 as “research in which the probability and magnitude of possible harms implied by participation in the research are no greater than those encountered by participants in those aspects of their everyday life that relate to the research” (p.22). Minimal risk research is delegated for review by one or two REB members. **Above minimal risk research** applications are assigned for full board review.

A number of other risk assessments are conducted including considerations of emotional, employment, social, and physical risks to participants, the community, and to researchers. The final assessment of whether the proposed study adheres to ethics standards in the TCPS 2 is ultimately made by the REB which considers a range of factors, including risks (e.g., the nature of risks, vulnerability of participants, how risks will be mitigated).

RESEARCH ETHICS REVIEW SUMMARY

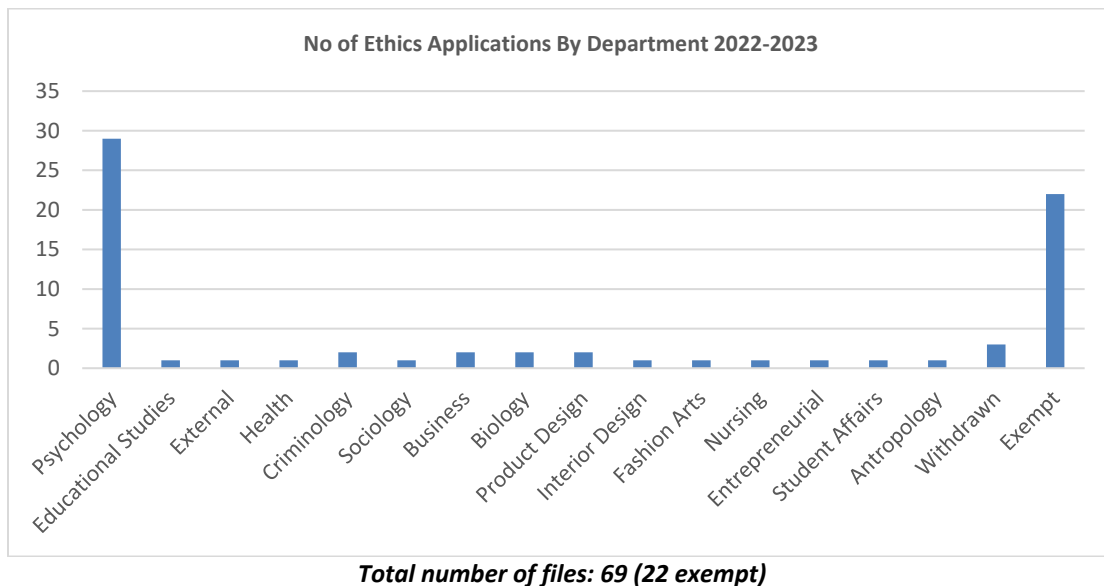
Part I: Ethics applications reviewed and approved September 1, 2022 – August 31, 2023

The REB uses the ROMEIO platform to manage and review applications. From September 1, 2022 to August 31, 2023, forty-seven REB applications were reviewed on ROMEIO. Three applications were withdrawn, with one deemed exempt from review and the other two were withdrawn by the researchers. The majority of ethics applications were submitted by KPU faculty researchers, with 2 out of 47 applications submitted by external applicants. All applications were reviewed by the Chair and one or two other REB members with expertise in the areas being reviewed.

Applications exempt from review

The Chair reviewed an additional twenty-two research projects and deemed them exempt from REB review.

Ethics applications by KPU department

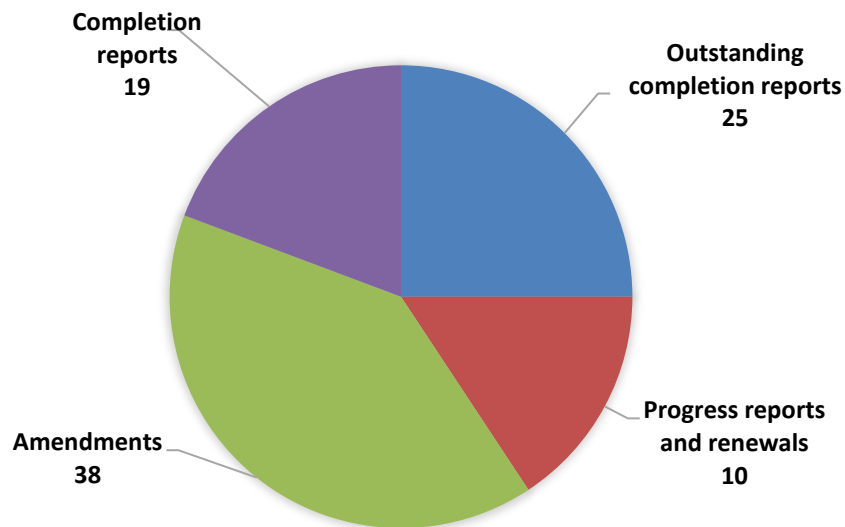


Post Approval Activities

The REB has a number of administrative controls while research studies are on-going. Researchers have the responsibility to provide an annual progress report for multi-year projects and to renew their REB approval before it expires. There were ten progress reports and renewals to extend the end date of the projects. Researchers are also responsible for submitting completion reports when data collection is complete. Nineteen completion reports were submitted and twenty-five were outstanding at the end of the year.

A central aspect of post-approval activities are amendments, which are changes to protocols after a study has been approved. Thirty-eight amendments were reviewed and approved. One post-approval amendment was deemed above minimal risk and was reviewed by the full board.

POST APPROVAL ACTIVITIES



Adverse events

The REB has a process by which research participants can submit complaints as well as adverse events notifications for researchers. Any adverse events must be documented by the research team and reported to the REB as soon as possible. One adverse event involving a research participant was reported to the REB. The study was halted in order to consult with the participant and PI. Recommendations from the consultations were implemented before the REB voted to restart the research.

PART II: Multi-jurisdictional reviews

KPU REB is a member of the Health Research BC, which is part of the Michael Smith Foundation for Health Research.

“Research Ethics BC supports a provincial, harmonized system for research ethics reviews of multi-jurisdictional studies involving human subjects (i.e. involving the resources, people, patients or data from more than one BC institution). [...] Harmonization streamlines the ethics review and approval process, allowing for submission of a single ethics application across all partner institutions. It also standardizes processes among research ethics boards, ensuring review quality and compliance with national policies.”
(www.bcahsn.ca/our-units/research-ethics-bc)

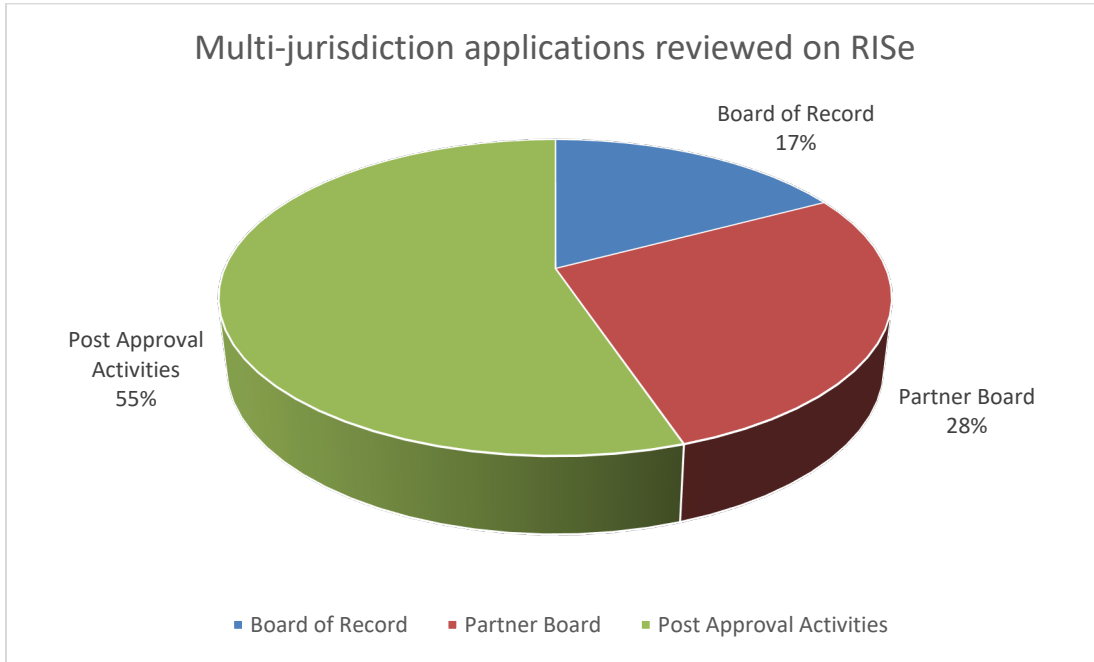
The harmonization review process is facilitated by the use of the Provincial Research Ethics Platform ([PREP](#)), housed within UBC’s RISE system.

As a member of Research Ethics BC, the REB partnered with other member REBs to jointly review twenty-nine ethics applications on PREP. The REB was **Board of Record** on five harmonized ethics applications and **Partner Board** on eight files. The REB also reviewed sixteen harmonized **Post Approval Activities**.

The REB Chair reviewed and entered provisos for all applications and **Post Approval Activities** for the KPU REB as both Board of Record and Partner Board.



Multi-Jurisdictional Ethics Applications Reviewed by KPU on PREP



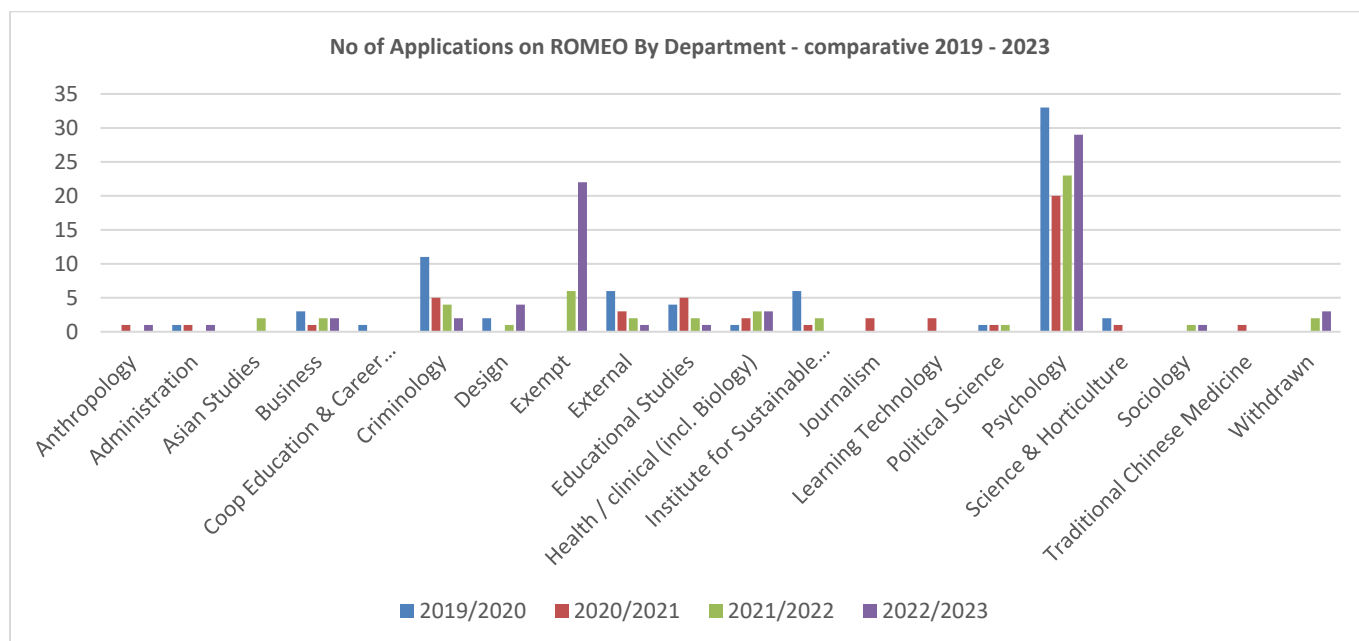
Twenty-nine harmonized applications were reviewed on PREP; 5 as the Board of Record, 8 as the Partner Board. Sixteen post approval activities were reviewed through the harmonization process.

In 2022-2023, the REB reviewed a total of **one hundred and forty-three** ethics applications:

ROMEO	RISE
✓ 47 applications	✓ 29 harmonized applications on PREP, including PAAs:
✓ 22 exempt applications	✓ 5 as Board of Record
✓ 38 post approval amendments	✓ 8 as Partner Board
✓ 10 progress reports	✓ 16 Post Approval Activities
✓ 19 completion reports	

PART III: Ethics Applications Reviewed and Approved 2019-2020 to 2022-2023

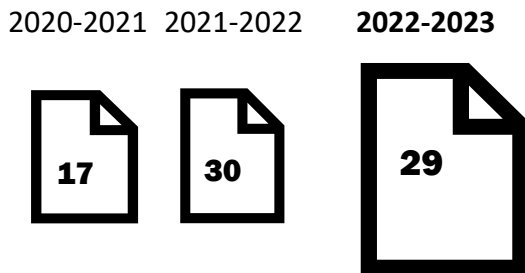
There were some changes in the volume of application compared to the previous year. However, the number of applications and amendments submitted through ROME0 and RISE are similar to previous years. There were significant increases in exempt applications because the REB implemented a process to better track these files.



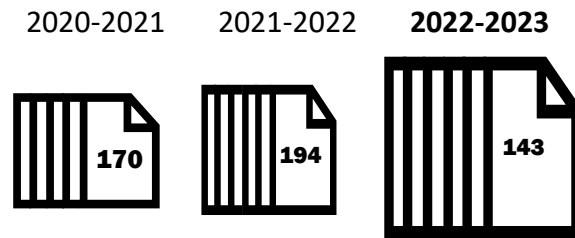
POST-APPROVAL ACTIVITIES ON ROME0

	<u>2020-2021</u>		<u>2021-2022</u>		<u>2022- 2023</u>
Amendments and Progress Reports	45	↑	57	↓	48
Completion reports submitted	62	↓	56	↓	19
Completion reports still Outstanding	27	↑	45	↓	25

MULTI-JURISDICTIONAL APPLICATIONS ON PREP



TOTAL APPLICATIONS ON ROMEO & PREP



PROFESSIONAL DEVELOPMENT

REBC's Research Ethics Board Administrators (REBA) meetings

The partnership with REBC continued to provide important professional development opportunities for the REB. The Chair and Coordinator attended REBC's Research Ethics Board Administrators (REBA) meetings. The meetings bring together research ethics board administrators and some REB Chairs from the REBC network. These meetings provided valuable opportunities to engage with colleagues from other REBs in the network as well as in-meeting learning and sharing. REBC also provided professional development opportunities outside of the REBA meetings. For example, there were presentations and information sharing regarding research with children and adolescents as well as Indigenous-engaged research ethics review.

REBA Community of Practice (REBA-CoP)

The Chair and Coordinator continue to be members of the REBA Community of Practice (REBA-CoP) where they work with colleagues on specific topics related to harmonization, PREP, etc. The meetings are a learning environment with a focus on mentorship, education and support. The REBs engagement with REBC also resulted in a number of opportunities to liaison and develop relationships with partner REBs in the province.

Research Ethics BC Retreat

The chair and coordinator attended a one-day retreat for REB administrators in BC on May 5, 2023. This was a very informative retreat with opportunities for networking. Sessions included group discussion of case studies and Harmonization 101.

Conferences

The Chair and Coordinator attended the Canadian Association of Research Ethics Boards (CAREB) conference *Impact & Effect: Connecting to Community through Research Ethics* (June 2023). Key

takeaways from the conference included workshops on enacting Indigenous research community engagement and National updates including new guidance on broad consent and multi-jurisdictional ethics review of minimal risk research.

Annual Retreat

The REB held its annual retreat in June with a focus on professional development in two areas: 1) data security and privacy, and 2) unique ethical challenges when reviewing SoTL applications. There were two speakers, Dr. Lilach Marom who spoke on “Theorizing Practice, Practicing Theory: Cases from the classroom”, and Adam Cullum, who gave a presentation titled, “Best Information Management Practices in Teaching, Learning and Research.”

NEW GUIDANCE DOCUMENTS & GUIDELINES POSTED ON THE REB SHAREPOINT SITE

<https://kpuemp.sharepoint.com/sites/Research/SitePages/REB-Templates-and-Resources.aspx>

The REB regularly provides the KPU research community with updated guidance documents, guidelines, and templates. This year the updates included:

- a. The REB application questions in ROME0 were revised to bring them up-to-date with current ethics policies and practices.
- b. New guidelines for undergraduate course-based student research.
- c. New course-based student research application questions in ROME0

The SharePoint site was updated with the new materials, and the items were announced on Today@KPU.

OUTREACH & COLLABORATION

The REB continued to engage in outreach with the KPU research community. This engagement was accomplished through a variety of activities including relationship building with specific departments, presentation to classes, and one-on-one consultations with researchers. A substantial amount of the Chair’s time was spent on one-on-one consultations with researchers. Additionally, the Chair and Coordinator consulted and engaged with a number of other KPU departments, including the Privacy office, on issues related to ethics as they arose.

Senate Standing Committee on Research & Graduate Studies

To support communication between the REB and KPU’s community of researchers, the REB Chair provided reports twice a year and presented each report to meetings of the Senate Standing Committee on Research & Graduate Studies.

REB MEETINGS & MEMBERSHIP

The REB's 2022-2023 membership was compliant with the [TCPS 2, Article 6.4](#). Members represented a range of disciplines and areas of expertise. The REB members were:

Name	Department
Dr. Tara Lyons , Chair	Criminology
Dr. Richard Le Grand	Psychology
Dr. Greg Simmons	Criminology
Aliyah Ali	Community Member
Dr. Zahia Marzouk	Educational Studies
Dr. Shayna Minosky	Psychology
Dr. Rebecca Yoshizawa	Sociology

One member finished their term August 31, 2023. Calls for REB member and community member were posted on Today@KPU and websites to fill the vacancies.

REB Meetings

The REB met ten times during the 2022/2023 academic year. Most meetings were held virtually via MS Teams. Melissa Cuthill, the Research Data Management Librarian presented on KPU Research data management Policy at the March 2023 REB meeting.

ACKNOWLEDGMENTS

The REB would like to thank the REB Coordinator, Foluso Fagbamiye, for her professionalism and administrative support. We thank Dr. Deepak Gupta, AVP, Research, Innovation and Graduate Studies, for his on-going support to the REB. Dr. Gupta's collaborative leadership style and commitments to research and research ethics are appreciated.

DEFINITIONS

Board of Record – The Board of Record (BoR) for a multi-jurisdictional study is decided based upon the location of majority of participants and/or study team; as well as which institution is best placed to mitigate risk to participants/data.

Exempt – Not categorized as research as defined by the TCPS 2.

Harmonized review – A streamlined ethics review and approval process that allows for submission of a single ethics application across partner institutions. This applies to all minimal risk and above minimal risk ethics applications.

Partner Board – A partner board is an REB selected based on being a research site to jointly conduct a harmonized review of an ethics application with other REBs involved in the same study.

Post Approval Activity (PAA)– Amendments or changes after a study has been approved. PAAs take place after an application has received REB approval and a certificate of approval has been issued.

Principal Investigator (PI)- The Principal Investigator is the main person responsible for conducting the research, data analysis, report findings and compliance with policies, terms and conditions of approval.

Provincial Research Ethics Platform (PREP)- This is a new functionality within UBC's Human Ethics module used to review BC's harmonized studies.

Provisos – Provisos are questions or requests from the Research Ethics Board to the PI regarding the application.

RISe – The Provincial Research Ethics Platform (PREP) for harmonized studies is hosted by UBC's Research Information System Enterprise (RISe) software.

ROMEO – Research software for ethics applications and review.