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# FHREB ANNUAL REPORT: 2022-2023

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## Introduction

The Fraser Health Research Ethics Board (FHREB) is established and empowered under the authority of the VP responsible for Research to review and approve all research involving human participants in Fraser Health jurisdiction and/or under Fraser Health auspices, as defined by the Fraser Health Research Policy, prior to the initiation of any research related procedures.

In accordance with the Fraser Health Policy on Ethical Conduct of Research and Other Studies Involving Humans and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2), the FHREB is required to provide an annual report of activities conducted to the Fraser Health Board of Directors.

## Authority & Purpose

The purpose of the FHREB is to protect the rights and welfare of human participants enrolled in research. The FHREB reviews and oversees the research to ensure that it meets ethical principles and that it complies with all applicable regulations and guidelines pertaining to human participant protection. These include, but are not limited to, the Food and Drugs Act and applicable Regulations, the International Council on Harmonization Good Clinical Practice Guidelines, the Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, and where applicable, US Federal Regulations.

The FHREB has the authority to ensure that all research conducted under its oversight is designed and conducted in such a manner that it protects the rights, welfare, and privacy of research participants.

Specifically, the FHREB has the authority to:

- Establish the ethics review processes, and provide research ethics oversight to ensure the ethical conduct of the research,

- Approve, require modifications to, or disapprove, any research activity that falls within its jurisdiction,
- Ensure that the researcher has policies and procedures to protect the rights, safety and welfare of research participants,
- Request, receive and share any information involving the research that the REB considers necessary to fulfill its mandate, while maintaining confidentiality and respecting privacy,
- Conduct continuing ethical review to protect the rights and welfare and privacy of research participants,
- Suspend or terminate the ethics approval for the research,
- Place restrictions on the research,
- Take any actions considered reasonably necessary, and consistent with policies and procedures, to ensure the protection of the rights, safety, and well-being of participants in research conducted under the FHREB's jurisdiction.

## Board composition & administrative supports

As of March 31, 2023, the FHREB is composed of 11 members. No new members joined the FHREB in the past fiscal year.

	<b>VOTING MEMBER NAME FIRST LAST</b>	<b>HIGHEST DEGREES EARNED</b>	<b>PRIMARY SCIENTIFIC OR NONSCIENTIFIC SPECIALTY</b>	<b>AFFILIATION WITH INSTITUTION</b>
1	*Stephen Pearce Male / Canadian Citizen	MD, FRCPC	Cardiology	Yes
2	*Lindsay Meredith Male / Canadian Citizen	PhD	Business, Ethics	No
3	** Anu K. Sandhu Female/Canadian Citizen	LLB	Law	No
4	** Tamsin Miley Female / Canadian Citizen	LLB	Law	No
5	Zhenyi Li Male / Canadian Citizen	PhD	Community Member	No
6	Samar Hejazi Female / Canadian Citizen	PhD	Epidemiologist	Yes
7	Kim Macfarlane Female / Canadian Citizen	BSN, MA	Tertiary Critical Care	No
8	Bonnie MacKenzie Female / Canadian Citizen	BA	Community Member	No
9	Tim Leung Male / Canadian Citizen	PharmD	Pharmacy	Yes
10	Mickaël Francoeur Male / Canadian Citizen	MD, FRCPC	Emergency Medicine	Yes
11	Jeff Kerrie Male / Canadian Citizen	MD, FRCPC	Internal Medicine, Ethics	No

Administrative support for the FHREB is provided by 3.0 FTE position in the REB Office in the Department of Evaluation and Research Services (DERS): the Research Ethics & Compliance Manager, Research Ethics & Regulatory Specialist, and Research Ethics Coordinator. Additional support for the FHREB functions is provided by the DERS Program Assistant.

## FHREB Education

Ongoing education for REB members was delivered through staff-led sessions during the regularly scheduled full board meetings as well as via provincial education sessions organized by Research Ethics BC (REBC).

- Technology & Third Party Apps in Research, 2022 April 13 (delivered by S. O'Shaughnessy)
- Language Exclusions in Research, 2022 May 11 (delivered by S. Joolaie)
- TCPS 2 Updates, 2023 February 08 (delivered by S. O'Shaughnessy)
- Clinical Research Ethics Symposium, 2022 November 3-4 (delivered by REBC)

The REB Office staff also provide ongoing education and training to researchers, including the following workshops:

- Research Ethics Workshop for Chilliwack General Hospital Family Practice Residents, 2022 April 28
- Research Ethics Workshop for Surrey Memorial Hospital Family Practice Residents, 2022 August 11

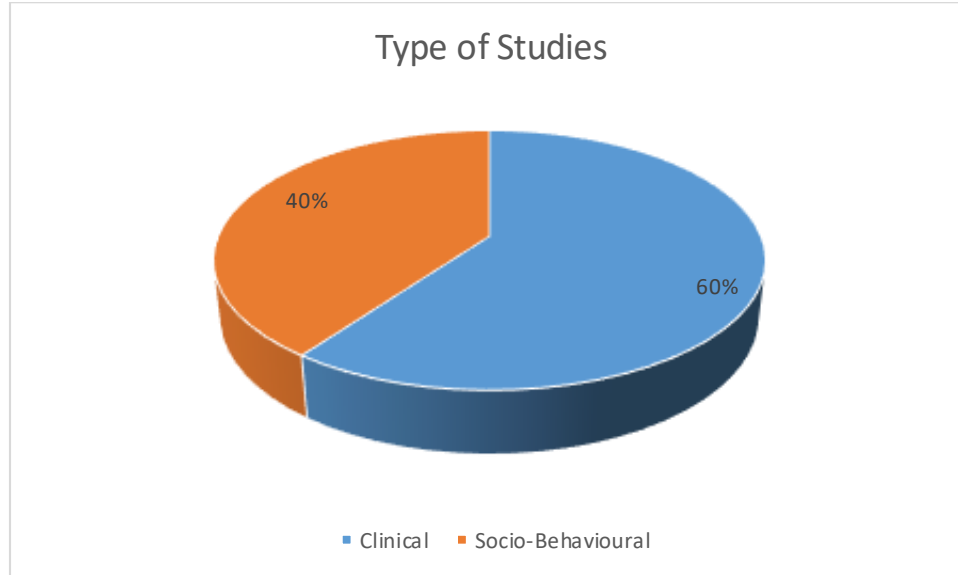
## Research Ethics Harmonization

Multi-jurisdictional research and research in partnership with academic institutions and health authorities in BC accounts for the majority of research submitted for review to the FHREB. REBC provides support for the provincial, harmonized system for research ethics review of multi-jurisdictional studies involving humans from more than one BC institution, including facilitating the Provincial Research Ethics Platform (PREP). The FHREB is an active partner in this initiative, including representation by Sara O'Shaughnessy, Research Ethics & Compliance Manager, on the REBC Advisory Council.

## Number of active studies at the end of fiscal

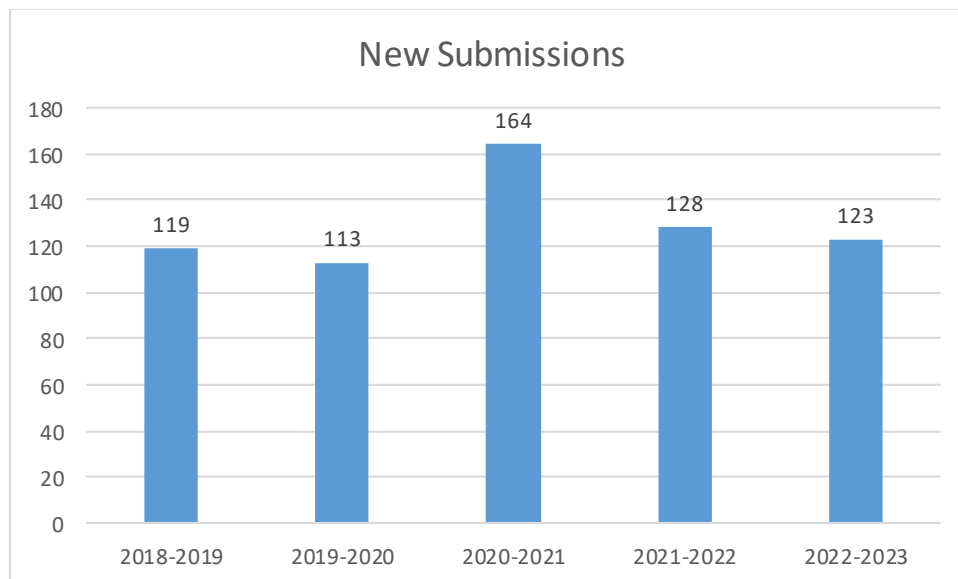
At the end of the fiscal year, there were 415 FHREB approved studies. 60 percent of these studies were clinical in nature and 40 percent were socio-behavioural in nature. Clinical research is defined as studies with the goal of improving the diagnosis, and treatment (including rehabilitation and palliation), of disease and injury; and improving the health and quality of life of individuals as they

pass through normal life stages. Behavioural research is defined as involving the study of human and social attitudes, beliefs, and behaviours in which no invasive procedures or measurements occur. Separate application forms exist for clinical and behavioural studies on both the Fraser Health ROMEO platform and the PREP platform to distinguish between submission types.



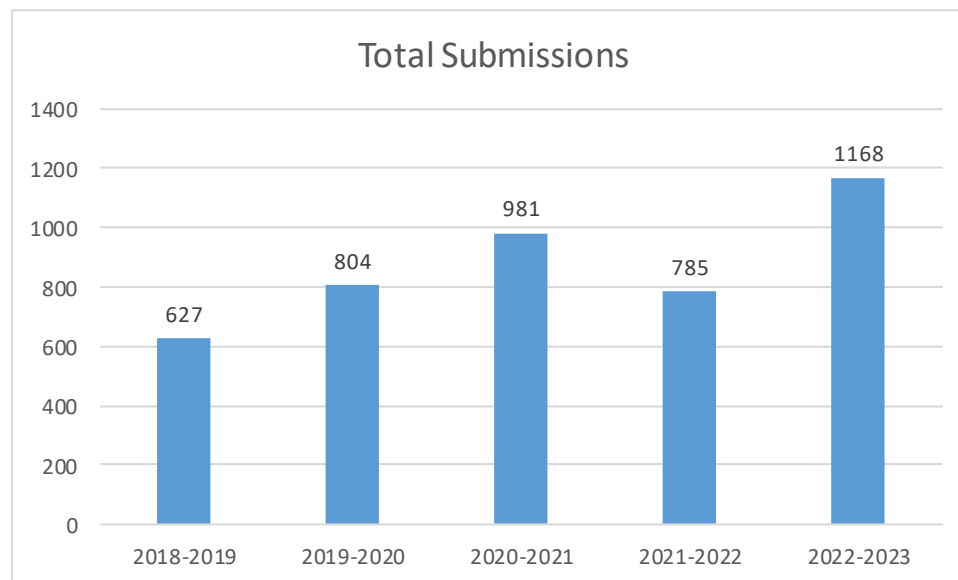
## Demand for review

During the 2022-2023 fiscal year, the FHREB received 123 new submissions for review. Of these, 15 were reviewed by the full board. The number of new submissions is slightly lower than in the previous fiscal year.



Eighty-two new submissions (67%) were submitted on the PREP platform, which is hosted on the UBC RISE system. Of these 82 new submissions, the FHREB served as the board of record (i.e. primary board responsible for the administration of the harmonized review) for 23 studies (28%).

Post-approval submissions also accounted for a significant portion of the demand for review. The FHREB received 475 requests for amendments, 305 requests for renewal, 148 requests for acknowledgements, and 86 requests for study close-outs. The total number of review requests is 1168, which represents a 49% increase from the previous fiscal year.



## Review timelines

The median timeline for submission of new studies to approval was 25.5 days. The median for studies submitted for harmonized review on the PREP platform was 28.5 days, and 14.5 days for new studies submitted on the ROMEO platform.

## Initiatives & Successes

The FHREB achieved a number of important successes over the 2022-2023 fiscal year, including a substantial update to the board's standard operating procedures (SOPs) to align with the Network of Networks (N2)/Canadian Association of Research Ethics (CAREB) templates. This initiative ensures FHREB compliance with regulatory requirements. The board also updated twelve guidance notes, including a substantial revision to the informed consent guidance note providing updated guidance

on electronic and remote consent, and created a structured process and guidelines for external peer review requirements. Another key initiative is the launch of the Initial Application for Retrospective Chart Reviews on the ROMEO system, which is tailored to the specific ethical consideration of retrospective chart reviews and eliminates unnecessary burden on researchers completing lengthy application forms. A new process for providing REB exemption letters was also launched, including the Initial Application for REB Exemption Letters on ROMEO.

## Conclusion

The undersigned are pleased to confirm that the Fraser Health Research Ethics Board has been in compliance with the Tri-Council Policy Statement: Ethical Conduct for Conducting Research Involving Humans and other regulatory requirements, as applicable, for the 2022 to 2023 fiscal year. The FHREB approved the 2022-2023 annual report at its July 12<sup>th</sup>, 2023 meeting.

Respectfully submitted,



Dr. Stephen Pearce

FHREB co-Chair



Professor Lindsay Meredith, PhD

FHREB co-Chair