

# **Fraser Health Research Ethics Board**



## **Annual Report**

April 1, 2018  
to  
March 31, 2019

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## 1. Introduction

The protection of the rights and safety of human research participants who voluntarily agree to participate in research is the keystone of any research study grounded in the principles of scientific validity and reliability. The integrity of the research process itself is dependent on the collection of data that is free from bias and thus must rely on the free and willing participation of research participants. Protecting the rights and safety of these participants is the fundamental purpose of the Fraser Health Authority's (Fraser Health) Research Ethics Board (FHREB); this oversight in turn protects the integrity of the research process.

The FHREB strives to render thoughtful, fair and reasonable decisions that are based on the ethical principles of beneficence, distributive justice, respect and non-maleficence, and in so doing has established relationships with Fraser Health researchers that are based on trust and mutual respect. The outcome of the FHREB's due diligence in carrying out its review of new and continuing research studies is an ongoing improvement in the overall quality of the research conducted in Fraser Health, in addition to researchers' knowledge about the requirements for conducting ethical research.

Over the past year, the FHREB continued to clarify its standard requirements for research submissions, kept abreast of national and provincial changes in guidelines and legislation that affect decisions regarding the ethical approval of research studies, provided ongoing education and continued to be responsive to the inquiries of our research community.

This report is one aspect of the FHREB's effort to maintain the transparency and accountability of the research ethics review process in Fraser Health. The FHREB is very pleased to present its twelfth annual report for the 2018-2019 fiscal year. Any questions about this report may be directed to the board Co-Chairs, Dr. Stephen Pearce and Professor Lindsay Meredith.

## 2. The Fraser Health Research Ethics Board

### 2.1 Composition of the Board

As of the end of this fiscal year, the FHREB included 12 full time members, two of which shared the role of legal representative. The credentials, roles, affiliation with Fraser Health and terms of office for each member are described in Table 1.

**Table 1: 2018-2019 FHREB Membership List**

	<b>VOTING MEMBER NAME FIRST LAST</b>	<b>HIGHEST DEGREE S EARNED</b>	<b>PRIMARY SCIENTIFIC OR NONSCIENTIFIC SPECIALTY</b>	<b>□ TERM</b>	<b>AFFILIATION WITH INSTITUTION</b>
1	*Dr. Stephen Pearce Male / Canadian Citizen	MD, FRCPC	Cardiology	August 07, 2018 to August 07, 2021	Yes
2	Dr. Allan Belzberg Male / Canadian Citizen	MD, FRCPC	Nuclear Medicine	March 10, 2017 to March 10, 2020	Yes
3	*Prof. Lindsay Meredith Male / Canadian Citizen	PhD	Business	February 07, 2019 to January 30, 2020	No
4	** Anu K. Sandhu Female/Canadian Citizen	LLB	Law	June 08, 2018 to June 08, 2021	No
5	** Tamsin Miley Female / Canadian Citizen	LLB	Law	March 08, 2017 to March 08, 2020	No
6	Zhenyi Li Male / Canadian Citizen	PhD	Community Member	March 08, 2017 to March 08, 2020	No
7	Samar Hejazi Female / Canadian Citizen	PhD	Epidemiologist	January 31, 2018 to January 31, 2021	Yes
8	Kim Macfarlane Female / Canadian Citizen	BSN, MA	Tertiary Critical Care	November 22, 2016 to November 22, 2019	No
9	Dr. Jeff Kerrie Male / Canadian Citizen	MD	Internal Medicine, Ethics	August 27, 2018 to August 27, 2021	Yes
10	Michelle Tsai Female / Canadian Citizen	MA	Counselling Psychology	October 03, 2017 to October 03, 2020	Yes
11	Bonnie MacKenzie Female / Canadian Citizen	BA	Community Member	January 31, 2018 to January 31, 2021	No
12	Tim Leung Male / Canadian Citizen	PharmD	Pharmacy	March 12, 2018 to March 12, 2021	Yes
* Co-chair ** Alternate *** non-voting member □ Date of Appointment Letter Ex officio: Susan Chunick, Executive Director, Department of Evaluation and Research Services					

## 2.2 Responsibilities of the FHREB

The FHREB is responsible for review, approval and ongoing oversight of all research studies involving humans conducted by Fraser Health researchers at all Fraser Health sites. These researchers include Fraser Health employees, privileged physicians, affiliated academic researchers and any University of British Columbia medical student or resident who is completing research in the health authority as part of their academic requirements.

The FHREB operates according to the principles and standards detailed in the Government of Canada's national standard for research ethics, the Tri-council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2). In addition, the FHREB complies with Health Canada regulations and guidelines concerning the ethical review of clinical drug, device and natural health product trials, and with United States (U.S.) government legislation governing the ethical review of studies funded by their government agencies and/or regulated by the U.S.

Food and Drug Administration . The FHREB ensures that any other Canadian and provincial legislation that is applicable to the conduct of research by a public institution is adhered to by Fraser Health researchers.

In addition, FHREB members are specifically accountable for ensuring that the requirements of the Fraser Health policy The Ethical Conduct of Research and Other Studies Involving Human Participants are met which includes responsibility for determining the scientific and ethical integrity of each individual research study. Key responsibilities include ensuring that:

- 1) the study is of value and that the research methodology is sufficient to answer the research question;
- 2) all ethical norms related to recruitment of study participants, consent and study procedures, safety management and conflict of interest are complied with by the researchers, and that;
- 3) consent forms and data collection instruments comply with FHREB standards.

An additional role is assigned the FHREB Co-Chairs who conduct the delegated review of new studies that meet the criteria for minimal risk as defined by the TCPS2 and FHREB policy. The delegated review process is also used to review:

- 1) applications for amendment and renewal of previously approved studies that do not require full board review;
- 2) local and international serious adverse events and protocol deviations;
- 3) principal investigator responses to requests for modifications arising from full board or delegated review, and;
- 4) any other study-related correspondence.

Please refer to Appendices 1 and 2 for terms of reference for the FHREB members and FHREB Co-Chairs.

## 2.3 Conflict of Interest

All FHREB members are required to complete a conflict of interest disclosure form (see Appendix 3) on an annual basis to ensure that any associations with industry sponsors of research or research team members are made known. Any members found to have a conflict of interest are excused from the review of the applicable research study.

## 2.4 FHREB Education

The annual education session for the FHREB was held on March 16, 2019 for this fiscal year. This session included a presentation by Dr. Stephen Hopton Cann, Clinical Professor in the School of Population and Public Health at UBC and Associate Chair of the Providence Health Research Ethics Board on the regulation of medical device trials in Canada. The session also

included a presentation by Ms. Sarah Flann, Fraser Health Research Ethics and Regulatory Specialist, on ethical considerations in patient-oriented research.

Members of the REB staff and board also attended the UBC Clinical REB Education Session on October 3, 2018, and the Island Health REB Education Session on January 21, 2019.

In addition to the Education Sessions, the REB staff implemented regular educational activities in the board meetings in January 2019. Each month, a chapter of the Tri-Council Policy Statement 2, the guiding document for research ethics in Canada, is reviewed and discussed.

## 2.5 FHREB Honoraria

The FHREB members are each paid a monthly honorarium of \$450.00 for their participation with \$850.00 being paid to the Co-Chairs. This honoraria is funded by the \$4,000.00 fee for the ethical review of new applications that are paid by industry sponsors for research studies conducted in Fraser Health.

# 3. Ethical Standards and Services

## 3.1 FHREB Standard Requirements

A substantial review of the FHREB Guidance Notes, application forms, and consent form templates was undertaken by the REB Office during this fiscal year to ensure information on our website is aligned with current regulations, best practices, and ethics guidance. See Appendix 4 for the revision status of each document.

## 3.1 Access to Fraser Health Data

Working with the Fraser Health Privacy Office, a process was implemented to prioritize the review of time-sensitive clinical trials and to minimize the time needed to review minimal risk research when the data is retained within the Fraser Health network on the M: drive. In addition, regular meetings are held with the Privacy Office to ensure mutual understanding of requirements for data access and timelines for review of the data requests. The Privacy Office also clarified that research studies review and approved by the FHREB that utilize survey methodology are exempt from Privacy Office review and approval.

The board is very grateful to the Fraser Health Privacy Office for their support of these initiatives.

## 3.2 Standard Operating Procedures

The FHREB Standard Operating Procedures (SOPs) were substantially revised over the 2017-2018 and 2018-2019 fiscal years, with finalized versions created in 2018-2019. The FHREB voluntarily adopted the Canadian Association of Research Ethics Board standard operating procedure templates to ensure a high standard of quality. Three additional SOPs specific to FHREB internal practices, including management of harmonized studies, the Fraser Health research privacy review process, and management of Tri-Council funded studies were created.

## 3.3 Research Quality Improvement Program

Two studies were inspected by Ms. Sarah Flann during the 2018-2019 fiscal year. The results of the inspections were presented to the Board at the April FHREB meeting of the following fiscal year.

## 3.4 Research Ethics Education

Six workshops that included research ethics content were conducted for Fraser Health researchers and for University of British Columbia Family Practice residents; the latter who are required to conduct a research study during their residency in Fraser Health.

## 3.5 Research Ethics Website

All ethics review procedures, including meeting schedules, and applicable guidances, forms and templates are posted and updated on an ongoing basis to the Department of Evaluation and Research Services web site at <https://www.fraserhealth.ca/employees/research-and-evaluation/find-resources/research-forms-guidance-notes-templates#.XMhzF9pKi5s>.

In addition, a monthly report of the volume of active studies, those pending approval, funding status, and classification by program/area is posted at the beginning of each new month to the department's website.

# 4. Administrative Operations

## 4.1 Support

Susan Chunick is the Executive Director for the Department of Evaluation and Research Services with responsibility for developing, implementing and monitoring ethical review process



standards for Fraser Health, providing policy guidance to the FHREB, ensuring that Fraser Health is compliant with all applicable international, Canadian and provincial legislation, guidelines and standards, and for overseeing the administration of the FHREB. In addition, Ms. Chunick conducts workshops on the overall conduct of research for Fraser Health employees and privileged physicians and is a member of the provincial Seniors Leaders' Group for the Research Ethics BC harmonization initiative.

The FHREB office was staffed by one full-time Research Ethics and Regulatory Specialist (Sara O'Shaughnessy) and one part-time Research Ethics and Regulatory Specialist (Sarah Flann). The FHREB Specialists perform the essential function of ensuring that the board runs efficiently and effectively. This includes providing support to individual researchers, processing all applications for and decisions of the full board and delegated review, providing assistance to the FHREB Co-Chairs, participating in developing and presenting workshops on ethical review and updating forms, templates, guidance notes, standard operating procedures and policies. In addition to this and as a strategy to improve and sustain the consistency of ethical review, a pre-review of all initial and renewal applications, consent forms and other documentation submitted for full board and delegated review is conducted to ensure standard requirements are met. This information is included in the study documents sent to the board members prior to their attendance at meetings.

In order to ensure the sustainability of the service provided by the FHREB Co-Chairs, in 2015 the board decided that it would be appropriate to expand the duties of the FHREB Specialists and in congruence with the TCPS 2 2014 to include the review and approval of minimal risk studies for the following types of submissions:

- a. new minimal risk studies (input from Co-Chairs/REB members solicited as needed at the discretion of the FHREB Specialists);
- b. responses to modifications (if minor);
- c. annual renewal applications that do not require full board review;
- d. study close-out applications;
- e. minor amendment applications that do not constitute a change in the risk-benefit ratio (i.e. addition of study site, submission of new recruitment material, consent form language, change in FHREB contact information); amendments of a clinical nature would usually require review by the clinical REB Co-Chair, and;
- f. acknowledgements of administrative letters, e.g. data safety monitoring board reports.

In addition, the FHREB Specialists represented the FHREB on the Research Ethics BC Harmonization Initiative Advisory Committee. The FHREB Specialists also participated on provincial working groups to develop harmonized processes and procedures for investigator-sponsored clinical trials, chart reviews and revisions to the British Columbia Informed Consent Form Template.

The FHREB acknowledges the very high standards of effectiveness and efficiency with which both Dr. O'Shaughnessy, PhD, and Ms. Flann carried out their respective duties in support of Fraser Health research.

## 4.2 Customer Service

The FHREB office provides timely advice in response to inquiries from Fraser Health researchers and assistance in preparing applications for ethical review and related documentation upon request. These researchers include any Fraser Health employee or privileged physician engaged in research as well as academic researchers who have an affiliation agreement with Fraser Health for research purposes. The standard timeline for response to inquiries is within one business day. There were a total of 241 unique active principal investigators for this fiscal year who were engaged with the FHREB office.

## 4.3 BC Ethics Harmonization

The Fraser Health Research Ethics Board continued to be an active member of Research Ethics BC (formerly BC Ethics Harmonization Initiative) to harmonize the review of multi-jurisdictional studies. Effective April 9, 2018, the BC Academic Health Science Network (AHSN) partnered with the BC Ethics Harmonization Initiative Advisory Committee to move research ethics harmonization in BC from an initiative to a sustained entity rebranded as Research Ethics BC (REBC). AHSN will provide sustained funding and infrastructure, including the staffing of two part-time REBC Unit Directors and a full-time REBC Research Ethics Navigator, to maintain and expand the collaborative work being done by partner institutions to provide high-quality harmonized ethical review in BC.

The BC Ethics Harmonization Initiative Reciprocity Agreement signed by the senior leaders at REBC partner institutions expired April 15, 2018. With the agreement open, REBC is working with non-REBC institutions to expand membership and bring them into the REBC framework. An updated Memorandum of Understanding is forthcoming in the 2019-2020 fiscal year.

The most significant achievement over the past year has been the Fraser Health REB Office contribution as members of the REBC Advisory Committee to the development of the new Provincial Research Ethics Platform (PREP). PREP is an online research application system for all multi-jurisdictional reviews of harmonized research ethics submissions in BC as of November 30, 2018. PREP includes a Fraser Health module for researchers to input information specifically required by the FHREB for ethical review of submissions occurring at Fraser Health sites.

The REB Office staff participated in a provincial working group to revise the BC Common Informed Consent Form Template. The template was implemented on February 07, 2019.

The FHREB staff have also actively engaged with REBC partners to develop a framework for the harmonized review of retrospective chart review studies, which was formally rolled out at the start of the fiscal year. Dr. O'Shaughnessy continues to lead a provincial working group to develop a harmonized clinical trials ethical review framework for non-industry sponsored multi-jurisdictional clinical trials. This work is ongoing.

During the 2018-2019 fiscal year, the FHREB received 67 requests for harmonized initial ethical reviews, which represents 56% of all initial applications received by the FHREB. The FHREB

served as board of record for 21 submissions and REBC partner institutions served as board of record for 46 submissions. This is a 31% increase from the 51 requests for harmonized initial ethical review received in the 2017-2018 fiscal year.

Fraser Health has also entered into academic affiliation agreements with 31 new affiliated investigators expanding their research into the Fraser Health Region. This is a 41% increase from the 22 new affiliated investigators signed into affiliation agreements during the 2017-2018 fiscal year.

Overall participation in the REBC has helped to increase our understanding of the operations and standards of each participating REB and has established much stronger working relationships.

#### 4.4 Optimizing Document Management and Workflow

The FHREB office continues to work with Information Management and Information Technology to improve the functionality of the initial ethics application form, with the intention of streamlining workflow processes and eliminating manual data entry into the administrative database (i.e., Access) for research and processing data. This project has encountered numerous challenges due to the limitations of the Access database. A request for funding was made to the Health Informatics & Information Technologies Committee for a new application portal and document management system in November 2018 in order to improve efficiency. The request was not successful and other avenues are being explored to replace the outdated Access database with a more tailored and efficient system that is in line with what other Research Ethics Boards in the province of similar size and volume use.

### 5. Research Ethics Board Output

The following section describes the demand for FHREB review in terms of requests for review, the FHREB workload in terms of the number of reviews conducted, and the efficiency of the review process.

#### 5.1 Demand for Review

All Fraser Health researchers and external researchers conducting studies under Fraser Health's auspices submit an initial application for ethical review for new studies which must be reviewed and receive approval by the FHREB before any research-related procedures can be conducted in the health authority or at any other research sites. The types of studies reviewed include clinical drug and device trials which are carried out by Fraser Health privileged physicians only, other types of clinical trials which investigate different types of therapeutic procedures and a variety of population health and health services research which is carried out across many healthcare disciplines.

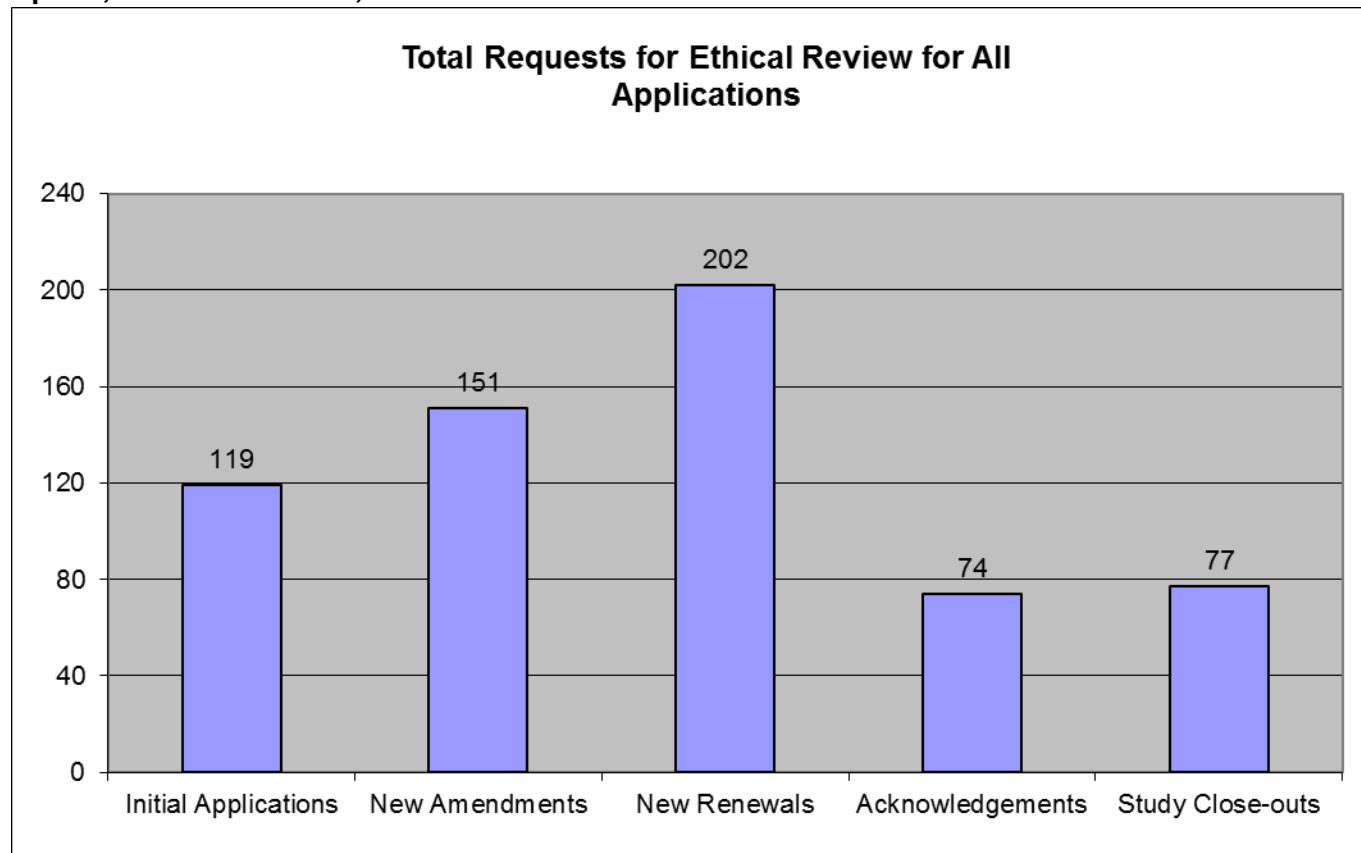
Applications for amendments to previously approved studies are also received throughout the year for studies that require changes to the research protocol, consent form(s) or other documentation. All amendments must be approved by the FHREB prior to implementation with the exception of those that require immediate implementation in order to ensure participant safety. Both Health Canada and the U.S. Food and Drug Administration require that the review of amendments for regulated clinical trials that meet prescribed criteria be conducted by a meeting of the full board.

In addition, annual renewal of previously approved studies is mandatory for all studies that are continuing to collect data directly from human participants, secondary data sources and/or tissue banks. Studies funded by the U.S. government and/or those regulated by their Food and Drug Administration must also be reviewed by the full board annually.

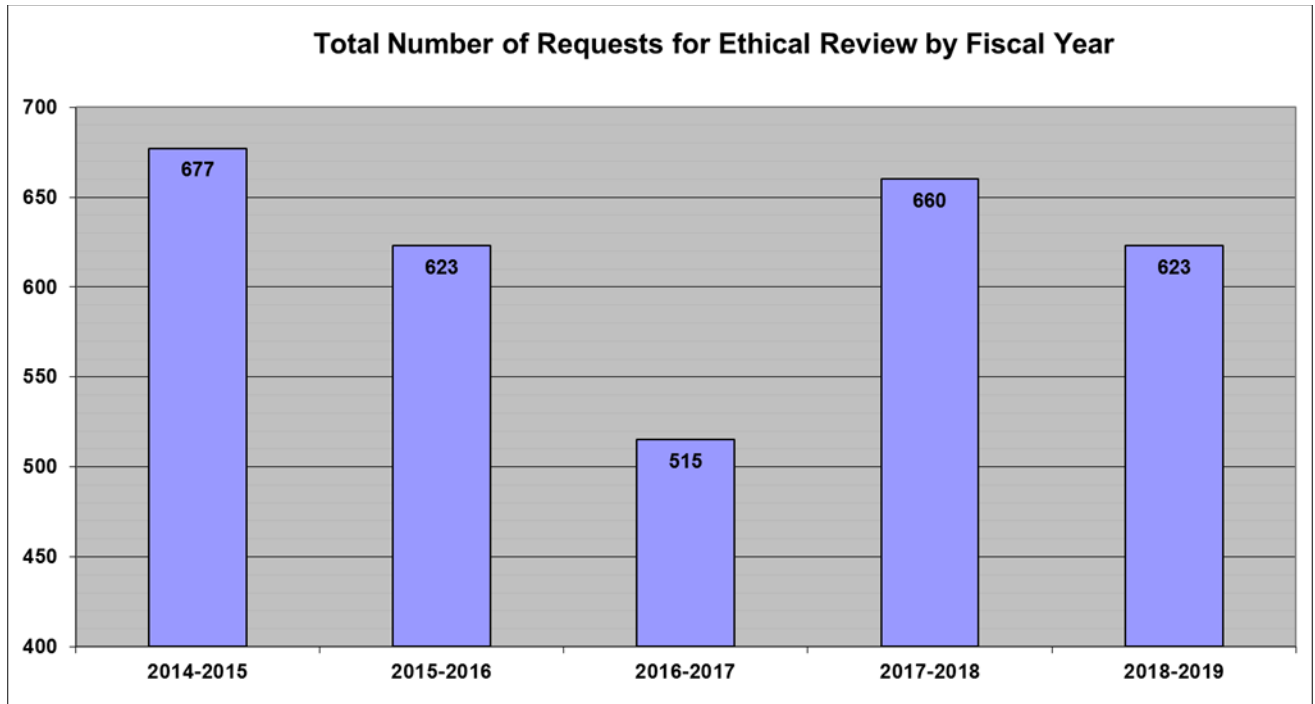
Other types of correspondence including notification of study closures or terminations, data safety monitoring board reports and protocol deviations, are acknowledged by the FHREB.

Throughout this fiscal year, 119 requests for initial ethical review were received for review by the FHREB, representing a 6% increase from the previous fiscal year. The overall demand for review of 623 applications of all types decreased by 6% compared to the 2017-2018 fiscal year. Figure 1 illustrates the volume of requests for review of all types of applications that were received. Figure 2 and Table 2 compares this distribution with the four previous fiscal years.

**Figure 1: Total Requests for Review of All Ethics Applications  $n=623$   
April 1, 2018 to March 31, 2019**



**Figure 2: Total Number of Requests for Ethical Review by Fiscal Year  
April 1, 2014 to March 31, 2019**



**Table 2: Type of Requests for Ethical Review by Fiscal Year from 2014-2019**

Type of Application	2014-2015	2015-2016	2016-2017	2017-2018	2018-2019
<b>Initial</b>	145	132	106	102	119
<b>Amendment</b>	169	147	115	170	151
<b>Renewal</b>	185	192	173	210	202
<b>Close-out</b>	73	69	68	62	74
<b>Acknowledgements</b>	105	83	53	115	77

## 5.2 FHREB Workload

Workload is differentiated from demand in that the data in this section reflects the actual number and type of applications that were reviewed in this fiscal year. The work of the FHREB includes the time to review all of the application documents and to make a determination regarding

approval as well as the time taken by the FHREB Office to prepare all pre-review material required for the board's review of each study.

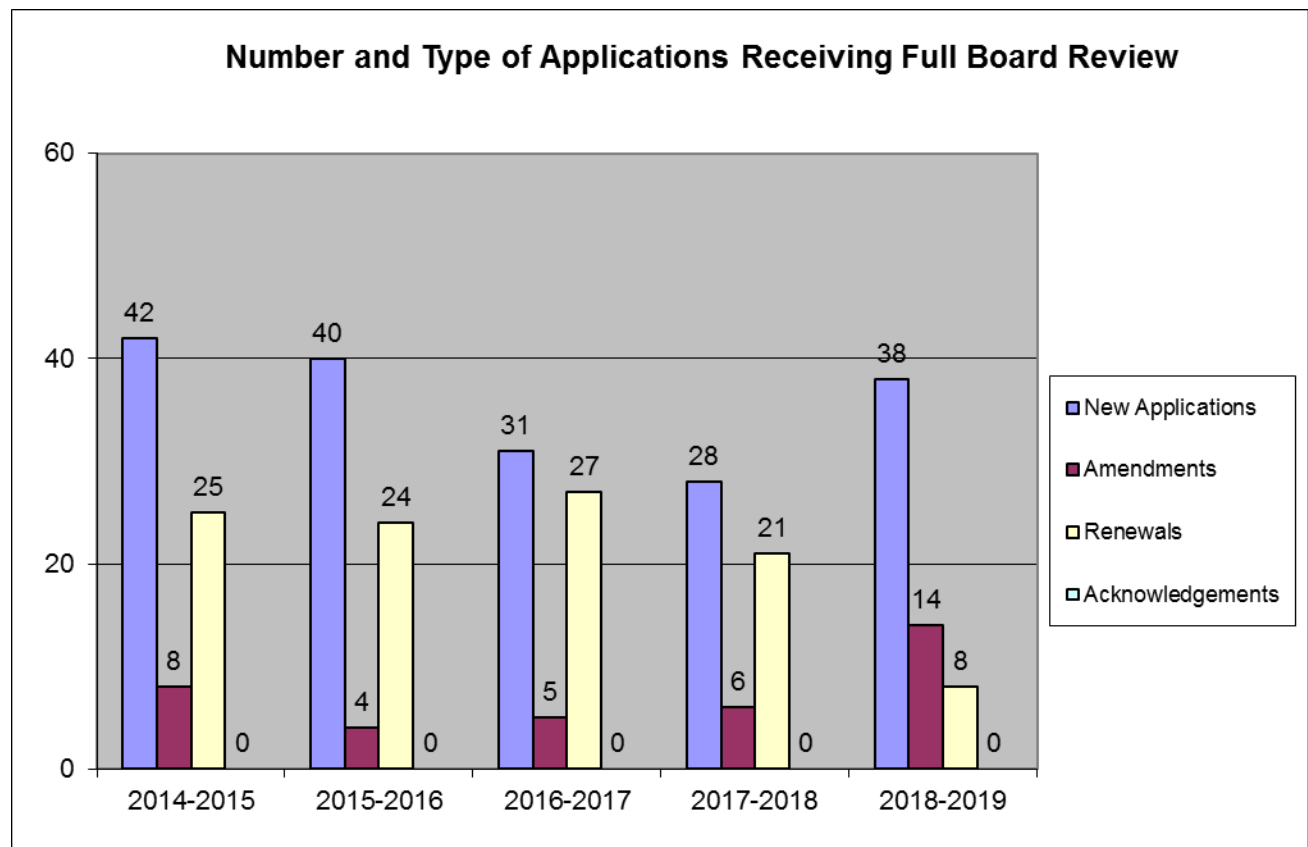
Workload varies from demand data because applications received late in the fiscal year may be reviewed in the following fiscal year. The FHREB reviewed a total of 657 applications (including acknowledgements of serious adverse event reports, protocol deviations, data safety monitoring board reports) for this fiscal year. This number is consistent with the prior fiscal year (n=656 in 2017-2018).

Figures 3 and 4 highlight the number and type of applications that received full board review and the number and type delegated to the FHREB Co-Chairs and REB Office for review from 2014 to 2019.

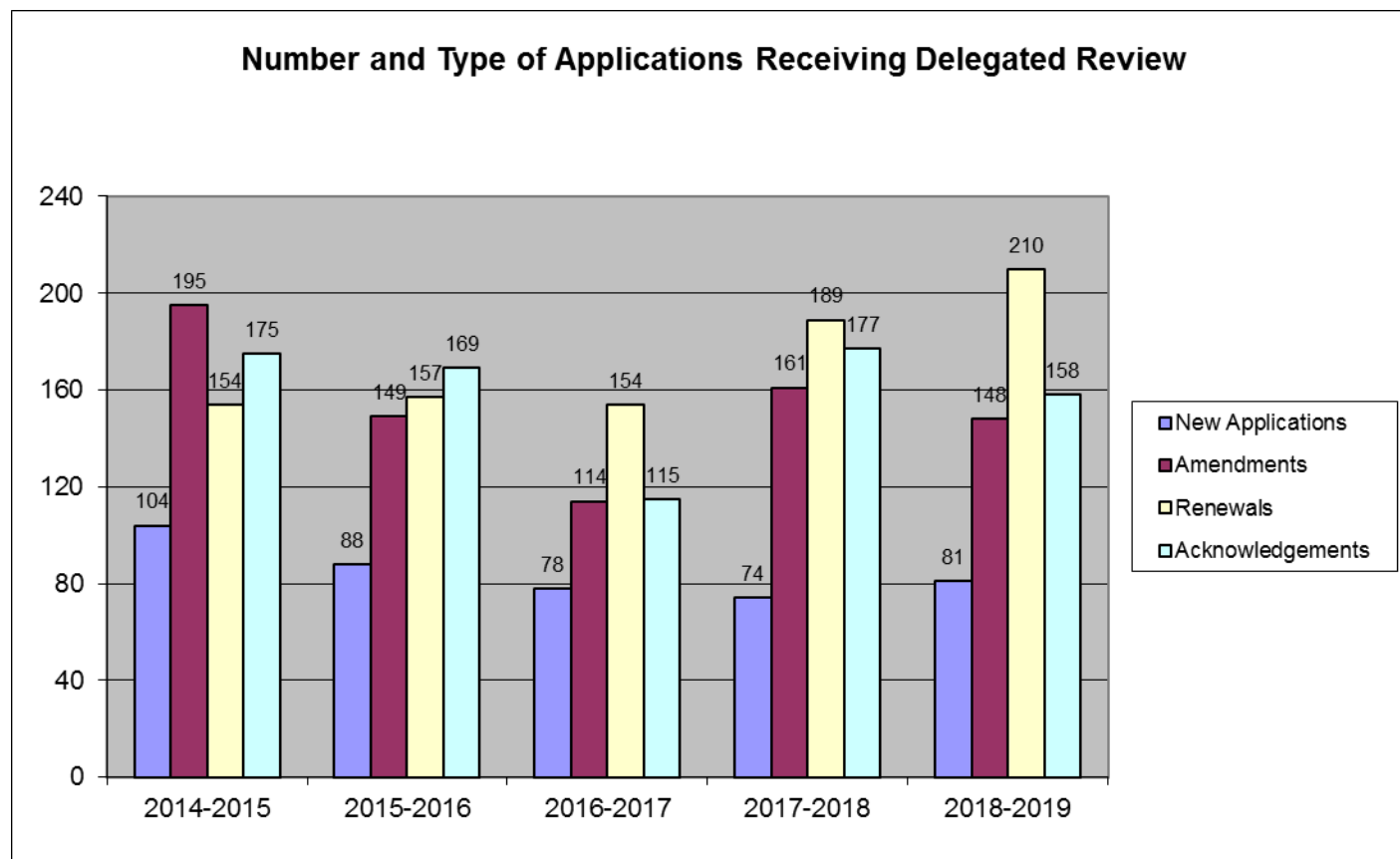
Delegated review occurs for new applications when the study is considered to be of minimal risk to the prospective subject or is retrospective in design, for amendments and renewals of active studies that do not require full board review, and for review of serious adverse events, protocol deviations and close-out reports.

Note that this data does not include subsequent modifications arising from either a delegated or full board review of initial or amendment applications that were conducted in the prior fiscal year. For this workload data, please see 5.2.2.

**Figure 3: Number and Type of Applications Receiving Full Board Review April 1, 2014 to March 31, 2019**



**Figure 4: Number and type of Applications Receiving Delegated Review  
April 1, 2014 to March 31, 2019**



### 5.2.1 Safety Reporting

Under delegated review, the review of safety-related information is one aspect of providing ongoing monitoring of active clinical drug and device trials. The aim of this review is to ensure that any unexpected serious adverse event (SAE) experienced by a local Fraser Health research participant has been handled appropriately and that any significant SAE pattern from other non-local sites is recognized.

Adverse events related to research studies are defined as "...noxious and unintended responses to a medicinal product related to any dose...". Non-local (i.e. international) SAE reports are those that are sent by the industry or academic sponsor to the principal investigator from other sites conducting the same study world-wide. The reporting process for these reports changed as a result of an agreement facilitated by the Canadian Association of Research Ethics Boards (CAREB) in July 2010. In accordance with the CAREB Guidance, non-local SAEs are now reported to the FHREB in the form of periodic safety update reports, accompanied by meaningful information that a research ethics board can assess. It is expected that the safety report(s) includes at a minimum, a sponsor analysis of the significance of the adverse event or an analysis from an independent data safety monitoring board, with (where appropriate) a

discussion of previous similar events. Investigators are advised that they may rely on the sponsor's assessment and provide to the FHREB a periodic safety update report prepared by the sponsor. These reports receive a delegated review only because the reports arise from research sites that are not within the FHREB's jurisdiction.

As a result of this change in reporting non-local SAEs, the FHREB reviewed all submitted non-local SAE reports and reviewed two SAE reports submitted for one local research study, none of which required further follow-up.

In addition to SAE reports, the FHREB Co-Chairs also review and follow up the outcome, if required, of reported protocol deviations related to clinical drug and device trials. A deviation is defined as an unanticipated or unintentional divergence or departure from the expected conduct of an approved study that is not consistent with the current research protocol, consent document or study addenda. Four protocol deviations were reviewed by the FHREB Co-Chairs. All deviations were managed appropriately by the principal investigators for the respective studies and did not require further follow up.

## 5.2.2 Disposition of the Review

Figure 5 illustrates the result (i.e. the decision) of the delegated and full board reviews. Studies that are not approved after initial review receive either a request for modifications or in the case of some studies receiving full board review where there are substantive concerns, may receive a deferral notice and therefore are deferred to a subsequent full board meeting upon receipt of the principal investigator's response. Note that not all studies are approved within this fiscal year because when the review is not finished it carries on into the following fiscal year; therefore only the activities of the 2018-2019 fiscal year are reported. Review and approval of the principal investigator's response to a request for modifications is delegated by the full board to one of the FHREB Co-Chairs under the delegated review process or if the changes are very minor, to the FHREB Research Ethics and Regulatory Specialists.

All principal investigators are expected to reply to the request for either modification or deferral within six months of the FHREB's decision, otherwise the study will be closed by the FHREB Research Ethics and Regulatory Specialists and the principal investigator notified of that decision. The principal investigator may submit the same study at a future time but with a new initial application so that it is reviewed as a new study.

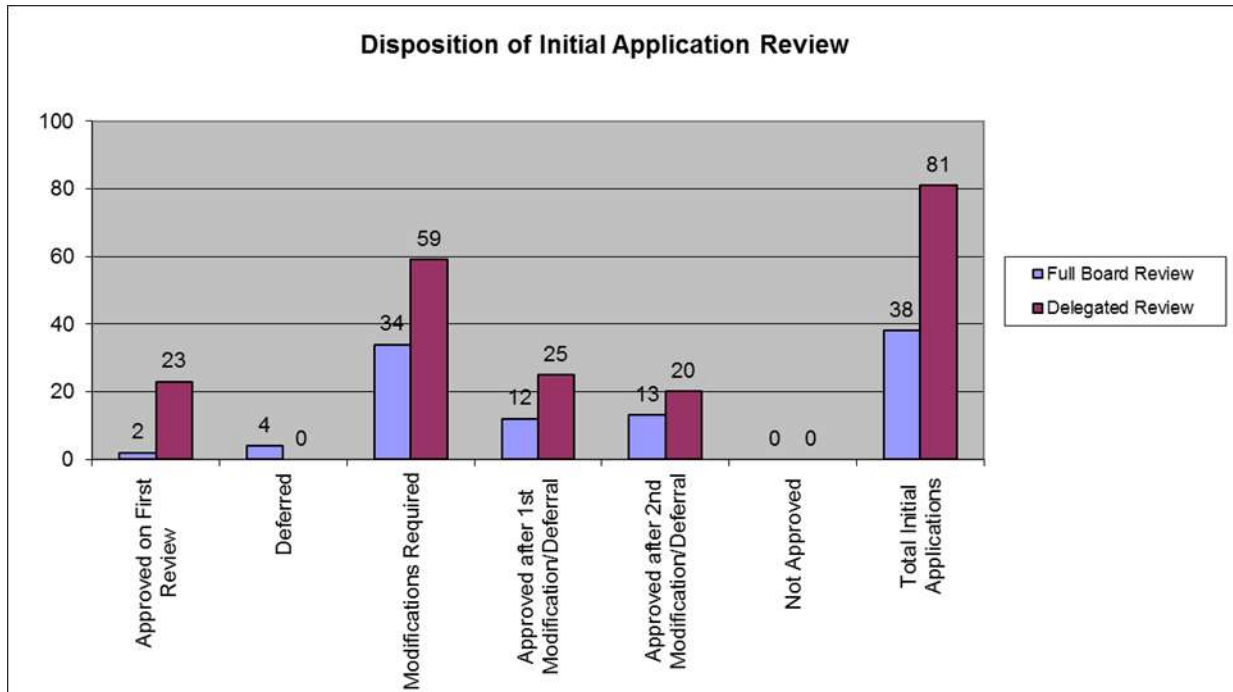
The FHREB has observed that more minimal risk studies require modifications compared to previous years and this change is attributed partially to an increase in the complexity of harmonized studies and the need for more information in research protocols. In contrast, the review of amendment and renewal applications for previously approved studies usually results in an approval decision because the amendment is most often a straight-forward change to the research protocol or consent form and the renewal is simply a report of year to date activity. Statistics for amendments and renewals are depicted in Figures 6 and 7.

Figure 5 also indicates that four full board studies were deferred. These studies required re-review by the full board because of substantive concerns regarding the scientific merit, research design or ethical issues relating to subject recruitment, consent or safety. Sometimes the



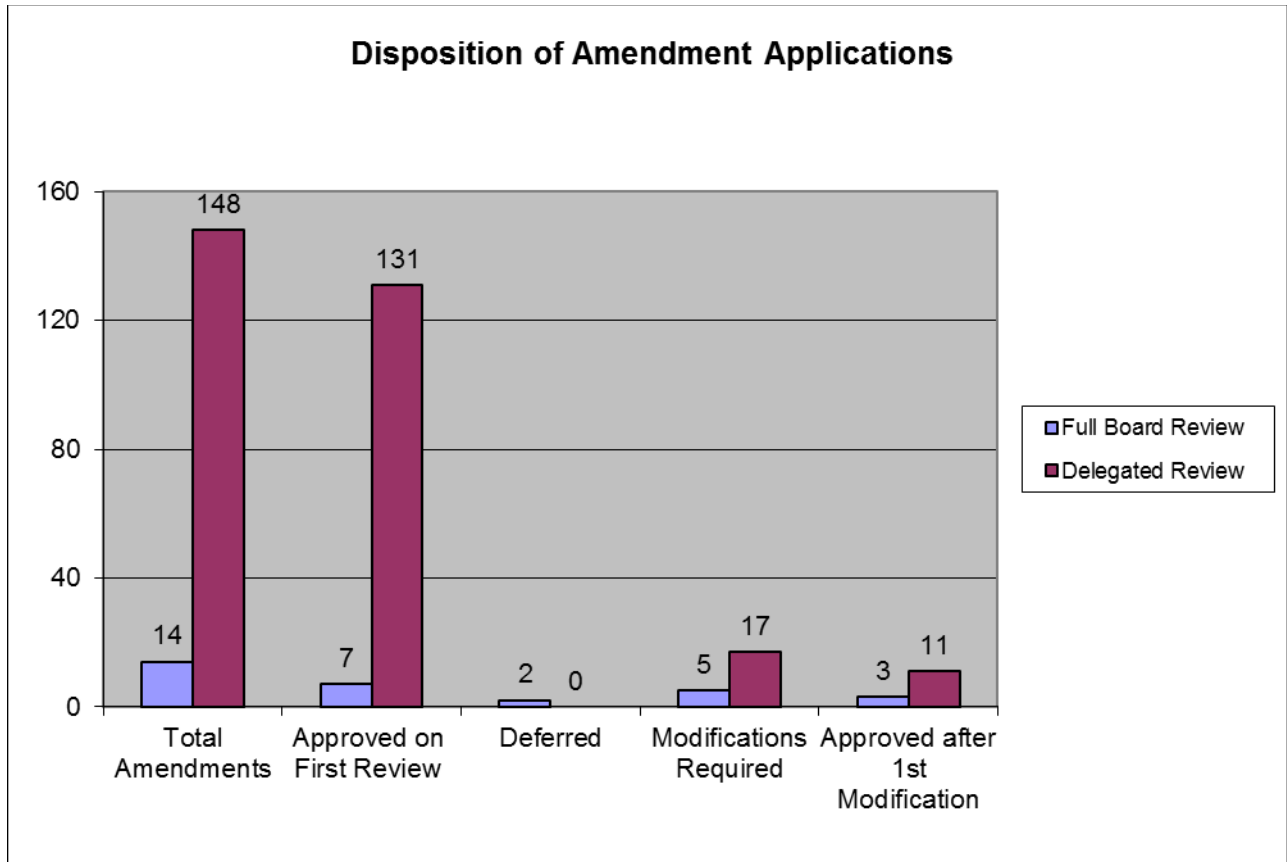
complexity of the ethical issues creates the need for a review process that is lengthy and involves more than one deferral. The FHREB offers the research team every opportunity to satisfy the FHREB of its concerns and does not limit the number of times that the study is submitted for review.

**Figure 5: Disposition of Review of Initial Applications by Full Board and Delegated Review  
April 1, 2018 to March 31, 2019**

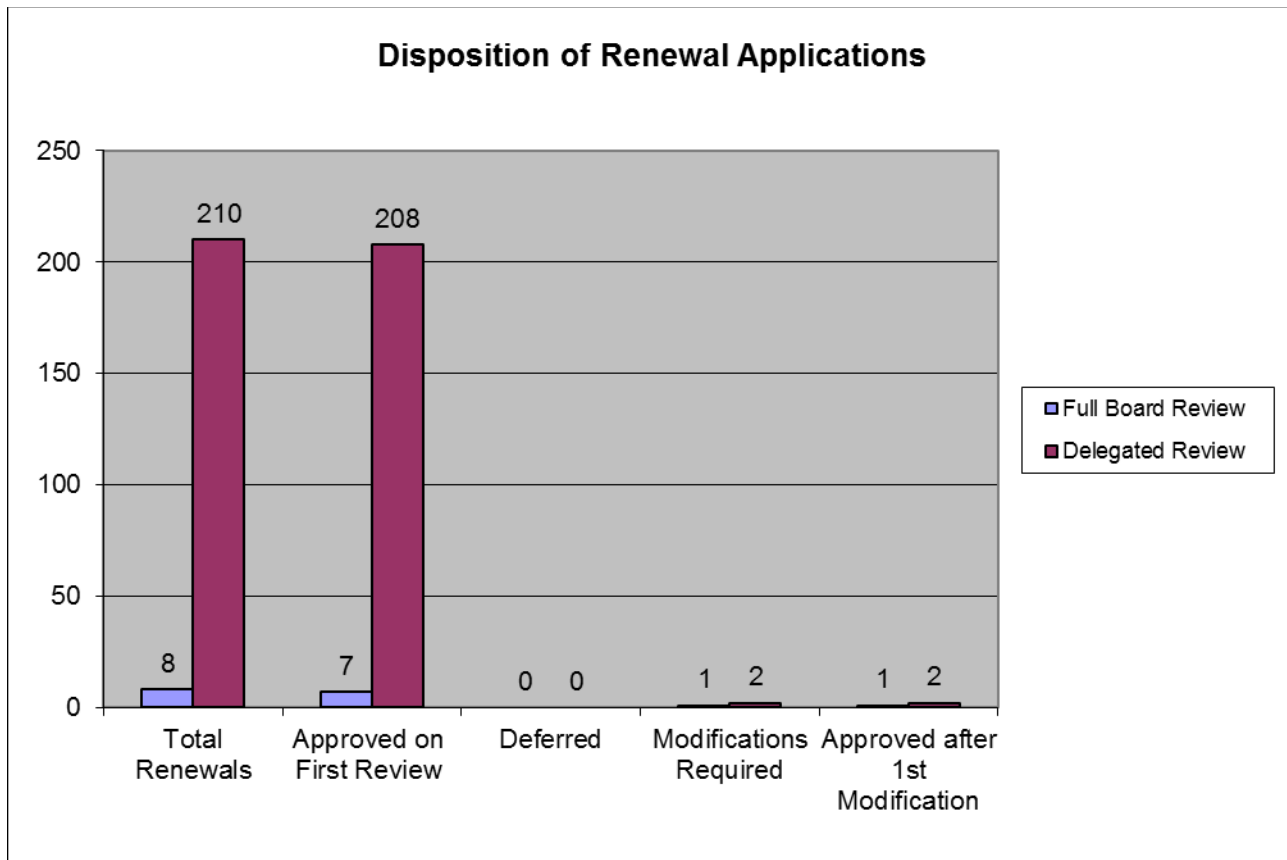


Figures 6 and 7 illustrate the disposition of the full board and delegated reviews for amendments and renewals of previously approved studies. As indicated, all but a very few are approved on initial review. Again, note that not all applications are approved within this fiscal year because when the review is not finished it carries on into the following fiscal year; therefore only the activities of the 2018-2019 fiscal year are reported.

**Figure 6: Disposition of Amendment Applications by Full Board and Delegated Review  
April 1, 2018 to March 31, 2019**



**Figure 7: Disposition of Review of Renewal Applications by Full Board and Delegated Review Received between April 1, 2018 to March 31, 2019**



### 5.2.3 Compliance with Annual Renewal

Annual renewal of previously approved studies is a mandatory requirement for all ongoing studies. In order to ensure compliance, a notice is sent to all principal investigators within one month of the expiry of the initial approval or subsequent renewal for their study. Forty-two studies (i.e. 21%) were renewed outside of the date of expiry which is one year from the initial date of approval or renewal. In spite of initiating an automatic renewal reminder notification system at the beginning of the fiscal year, the number of annual renewals outside of the expiry date is consistent with the prior fiscal year.

### 5.3 FHREB Efficiency

The FHREB office strives to issue decisions of the full board or delegated review within five business days of the review. The principal investigator must respond at any time within a six month period following the date of the decision, otherwise the FHREB will close the study.

The applications for full board review are received approximately three weeks prior to the full board meeting date to allow the FHREB Research Ethics and Regulatory Specialists time to pre-review the documents, coordinate harmonization of the files with partner REBs as applicable, and submit them to the FHREB members for review prior to the board meeting.

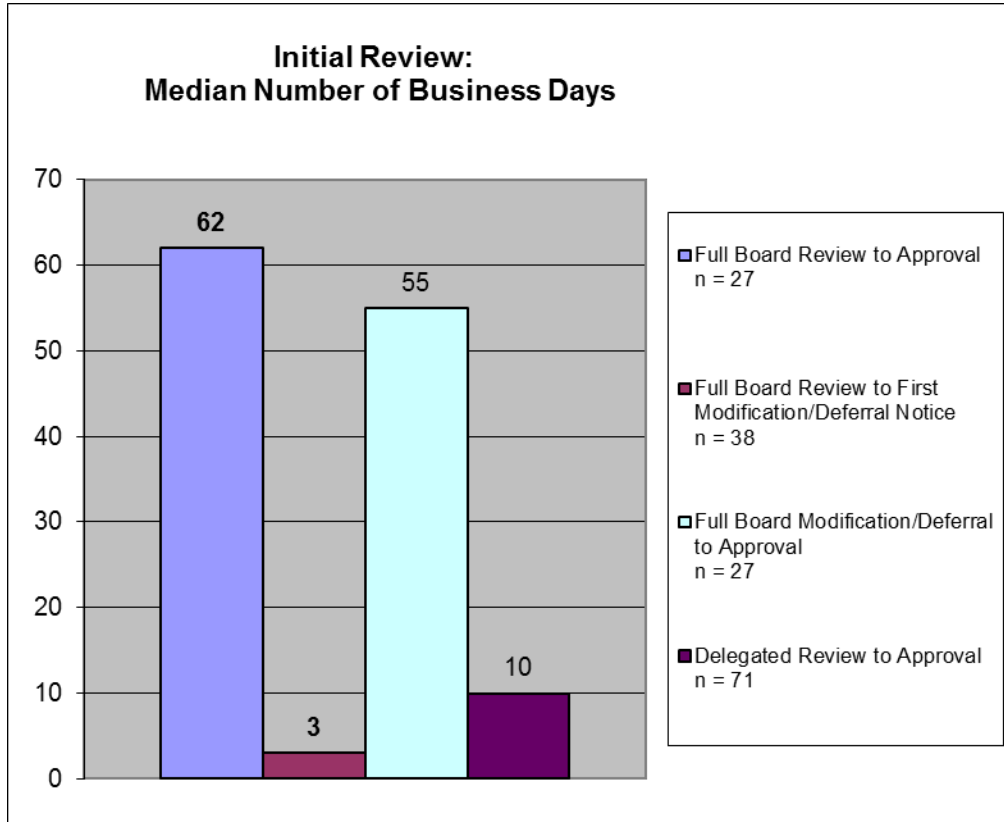
Figure 8 illustrates that the median number of business days for full board review from the date of the board meeting to approval is 62 days, with 10 days for delegated review. A portion of this time is attributed to the length of time it takes for the principal investigator to respond to the modification or deferral notice. It is important to note that this may also reflect the time it takes for an industry or academic sponsor to review and accept the required FHREB changes and to communicate their approval to the local Fraser Health principal investigator. As can be seen from the figure, the approval timeline is substantially shorter for delegated review.

In order to ensure oversight by the full board, a summary of all delegated reviews is sent to the members for any comment or questions that they may have before the ethics certificate of approval is issued to the principal investigator. All decisions are ratified at the next full board meeting.

Timelines are affected by the time spent by the REB Office on non-review tasks, such as participation in the REBC Advisory Committee, updating forms and other ethics documentation, coordination with the Fraser Health privacy office and managing ongoing administrative issues.

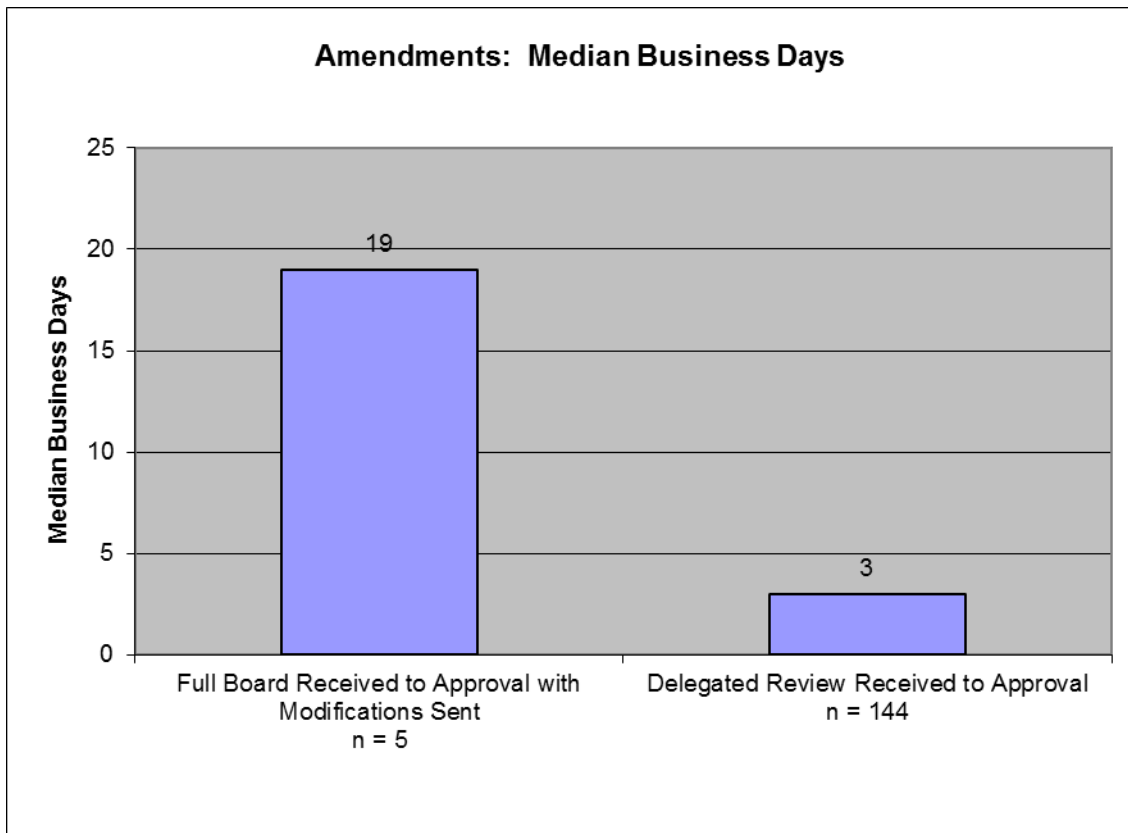
All timelines in the following figures are reported in median number of business days. Studies that were reviewed but did not receive final approval in this fiscal year are not included.

**Figure 8: Median Number of Business Days for Full Board and Delegated Review of Initial Submissions**  
**April 1, 2018 to March 31, 2019**



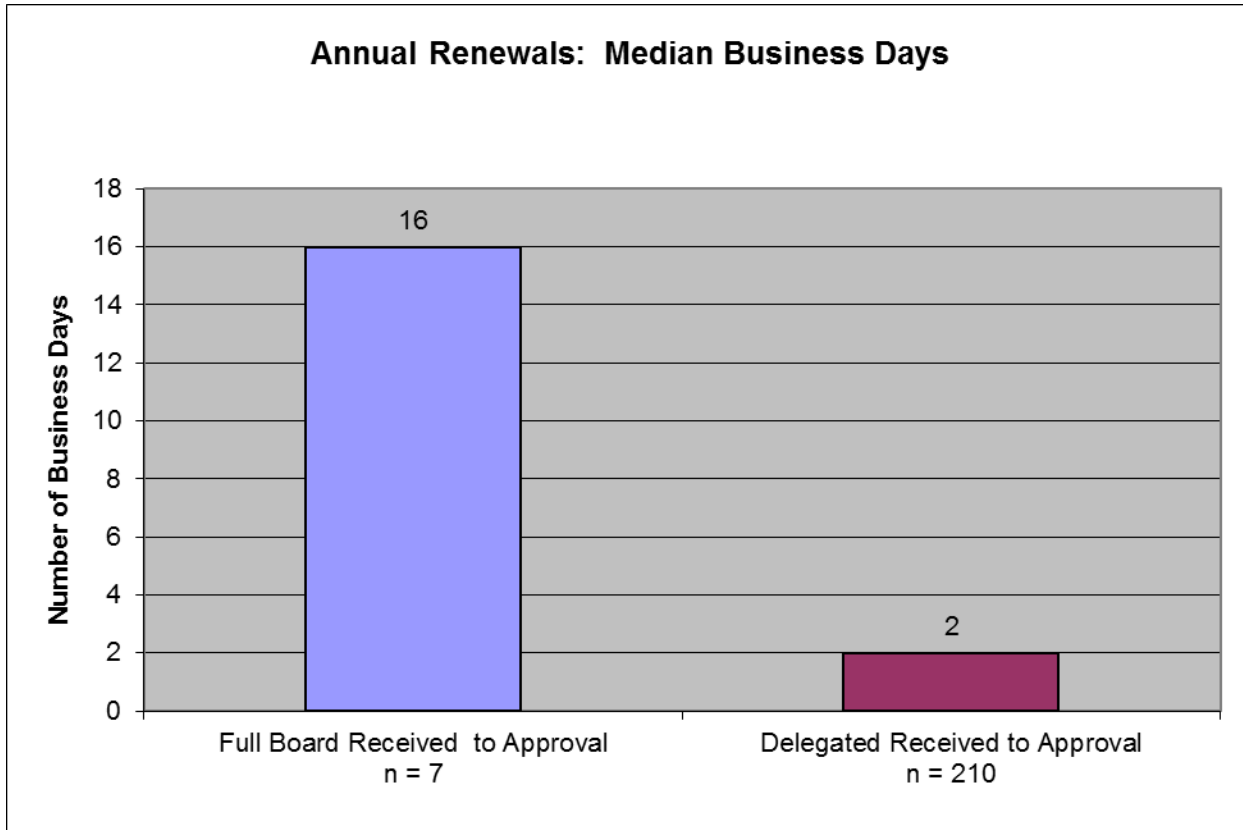
The timeline for amendment approvals is shown in Figure 9. The median number of business days for amendments for delegated review received to approval is three business days (n = 144). The median number of business days for full board amendments received to approved with modifications is nineteen (n = 5).

**Figure 9: Median Number of Business Days for Full Board and Delegated Review of Amendment Submissions  
April 1, 2018 to March 31, 2019**



The timeline for renewals is shown in Figure 10 illustrates the timelines for review of renewal applications.

**Figure 10: Median Number of Days from Date of Full Board and Delegated Review of Renewal Submissions to Approval Date April 1, 2018 to March 31, 2019**



## 6. Compliance with FHREB Requirements

### 6.1 Fraser Health Authority Research Inquiry and Investigation Committee

There were no referrals of research misconduct to the Fraser Health Research Inquiry and Investigation Committee for this fiscal year.

## 6.2 Breaches

There were four research-related privacy breaches reported to the Fraser Health Privacy Office and the FHREB in the 2018-2019 fiscal year.

## 6.3 Participant Complaints

There were no participant complaints in the 2018-2019 fiscal year.

# 7. Key Performance Indicators

The FHREB has developed the following key performance indicators (KPIs) as measures of compliance with ethical standards and of overall safety of research conducted in Fraser Health.

1. Compliance with the requirement for annual renewal of research studies set by Health Canada, the Canadian Institutes of Health Research, the U.S. Food and Drug Administration and the U.S. Department of Health and Human Services in order to maintain eligibility to either conduct clinical trials or receive funding for research. This KPI in addition applies to all research conducted in Fraser Health as it reflects adherence to ethical standards and Fraser Health research policies.
  - i. % of all regulated and non-regulated studies continuing to recruit and collect data from participants, access secondary data or tissue that are renewed within one year from date of initial ethical review or subsequent annual renewal: 79%
2. Serious Adverse Events.
  - i. # of Local Serious Adverse Events: 2
3. Participant Complaints, Appeals and Privacy Breaches: There were no participant complaints made to the FHREB, as noted on page 18. There were no requests for appeals of FHREB decisions brought forward by Fraser Health principal investigators to the Island Health Research Ethics Board; the Island Health Research Ethics Board functions as the appeal board for the FHREB. As noted on page 22, there were four research-related privacy breaches.

# 8. Challenges Ahead

The FHREB continues to evolve and keep current with best practices in the ethical review of research. As research ethics is always in evolution, the FHREB is sensitive to the desire of researchers for the application of consistent standards while at the same time striving to ensure that absolute requirements regarding ethical review continue to be implemented.



Provincial legislation, specifically the Freedom of Information and Protection of Privacy Act, includes research specific articles that are open to interpretation which therefore appear to be restrictive to Fraser Health researchers. The FHREB continues to work with the Fraser Health Privacy Office and our Legal Counsel to identify solutions to these issues so that research is not delayed. In addition, these have also been brought to the attention of REBC Chairs and Advisory Committee as clarification of the legislation is imperative for the review of multi-jurisdictional research.

The workload of the FHREB and the FHREB Office is significant, in particular, as the type of research reviewed increases in sophistication and multiple jurisdictions are involved in studies requiring multiple sources of data. Involvement in REBC has also taken a significant amount of time because of the amount of communication that the Research Ethics and Regulatory Specialists undertake between their counterpart REB administrators for multi-jurisdictional research. Maintaining efficiency of review for our researchers, including academic researchers affiliated with Fraser Health, is important with respect to customer service.

The REB Database, which records all submissions to the FHREB, continues to present challenges for the efficiency and functionality of the REB Office. The database was created in 2005 to run on Microsoft Access, a program that is no longer supported by Fraser Health, and does not provide any document management support. As a result, the current submission process relies on email submissions and manual filing of the supporting documentation. The study files are manually entered into the database as well. As such, this process is inherently inefficient and prone to human error. The initiative to eliminate manual data entry described in section 4.4 has not been successful due to the limitations of the outdated Access database. This database is unable to support the record-keeping and reporting requirements related to changes in the regulatory environment, the harmonization initiative, and substantial increases in submission volume since 2005.

## 9. Conclusion

The undersigned are pleased to confirm that the Fraser Health Authority 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 2017 to 2018 fiscal year. The FHREB approved the 2018-2019 annual report at its September 11th 2019 meeting.

Respectfully submitted,



**Dr. Stephen Pearce**  
FHREB co-Chair



**Professor Lindsay Meredith**  
FHREB co-Chair

## Appendix 1: Fraser Health Research Ethics Board Members Terms of Reference

APPROVED: 2007 August 09  
1st revision: 2007 October 17  
2nd revision: 2011 December 13  
**3rd revision: 2015 December 09**

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The members of the FH Research Ethics Board [FHREB] are responsible for carrying out the following activities and functions. The board operates under the authority of the FH Policy “The Ethical Conduct of Research and Other Studies Involving Human Subjects”.

1. Complete the “Introductory Tutorial for the Tri-council Policy Statement: Ethical Conduct of Research Involving Human Subjects” at <http://www.pre.ethics.gc.ca/english/tutorial/>
2. Review all submissions that meet the criteria for full board review that are assigned for a full board meeting prior to the meeting date. These include applications for initial ethical review, applications for amendment and renewal of previously approved studies that meet specific criteria for full board review, and responses to studies that have been deferred from a previous board review.
3. Submit written comments to the FHREB office at the conclusion of the REB meeting for compilation into the modifications or deferral memoranda.
4. Ensure that the study complies with the applicable Canadian federal and provincial and U.S. regulations when applicable and that all research complies with the current version of the Tri-Council Policy for Ethical Policy Statement: Ethical Conduct for Research Involving Humans and other non-regulatory requirements.
5. Make a decision about the outcome of the review for each study as follows:
  - a) approve if all FHREB requirements have been met satisfactorily, or
  - b) request that the investigator modify the study and/or respond to questions concerning the study prior to approval, or
  - c) refer to an external source for review, or
  - d) not approve.
6. Develop guidance notes, policies and procedures for ethical review in collaboration with the Executive Director, Department of Evaluation and Research Services, REB ex officio member.
7. Participate in educational activities, evaluations, audits or investigations related to the oversight of research ethics at FH.
8. Declare any conflict of interest pertaining to studies on the full board agenda before discussion begins.
9. Declare conflict of interest on an annual basis.

10. Specific responsibilities according to the expertise and role of individual members are:
- a. All Non-Scientific Members: are expected to provide input to areas relevant to their knowledge, expertise and experience, professional and otherwise. These members should advise the FHREB if additional expertise in a non-scientific area is required to assess whether the research protocol adequately protects the rights and welfare of subjects, and to comment on the comprehension of the consent document.
    - i. Community Member(s): are not affiliated with the Fraser Health Authority. They are expected to provide input regarding their knowledge about the local community, as it may relate to prospective subjects recruited from the local community, and be able to discuss issues and research from that perspective.
    - ii. Member(s) knowledgeable in relevant law: are expected to alert the FHREB to legal issues and their implications, and to present the legal views of specific areas that may be discussed, such as exculpatory language or provincial requirements regarding consent.
    - iii. Member(s) knowledgeable in research ethics: are expected to alert the FHREB to potential ethics issues basing their recommendations on a balance of ethics theory, practice and experience.
  - b. Scientific Members: are expected to contribute to the evaluation of a study on its ethical, scientific and statistical merits, and standards of practice. These members should also advise the FHREB if additional expertise in a scientific or non-scientific area is required to assess whether the research protocol, consent document and other research materials adequately protect the rights and welfare of subjects.
    - i. Methodologist: is appointed from the Department of Evaluation and Research Services staff. The methodologist provides analysis of the scientific merit of the study to ensure that the research design is appropriate for the stated research objectives and to ensure that the methodology and statistical analysis is commensurate with the study design.
    - ii. Pharmacist: is appointed from FH Pharmacy Services and ensures that the drug toxicity information included in Investigator Brochures and other relevant research related documents is included in the study consent form. This position also identifies flaws in study methodology.
    - iii. Other clinical experts: are appointed as needed according to the type of research reviewed by the REB on an ongoing basis. For example, a nurse researcher with expertise in qualitative research may be appointed. From time to time, ad hoc reviewers may be consulted for specific expertise or knowledge that is required in order to review the ethical acceptability of a proposal competently.
  - c. Ex-officio Member: Department of Evaluation and Research Services Executive Director
11. **[Approved 2015 December 09] Honoraria:** All REB members, excluding the co-Chairs, are paid \$450.00 per meeting attended.

- i. **Honoraria Paid to Non-FH Employees:** Cheques for the honoraria are sent directly to the REB members, who are physicians or non-FH employees by FH Finance, at the

address of their choice. There are no restrictions on the use of the honoraria by REB members who are non-FH employees or who are physicians.

- ii. **Honoraria Paid to FH Employees:** Honoraria for REB members who are FH employees may be claimed by that member with the submission of the following documentation to the Research Ethics and Regulatory Specialists:
  - a. expense receipts,
  - b. as per FH “Travel and Business Expense” policy, the expense claim must be filled out on an “Employee Expense Report”, and,
  - c. a written justification for that expense made to the Executive Director, Department of Evaluation and Research Services who will approve the request.

A cheque requisition form is sent to FH Finance for reimbursement of the approved funds to that REB member.

Honoraria to REB members who are FH employees may be used for the type of expenses that FH employees would normally be able to claim and that are related to the work of the Research Ethics Board. This would normally include expenses related to education, conferences, and other out-of-pocket expenses. Other expenses may be considered upon presentation of an adequate written justification.

Any purchase of equipment and supplies that is approved by the Executive Director, Department of Evaluation and Research Services must comply with the FH Research Policy Section 4.3c.

**Reference:** Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada. *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. 2014. Articles 6.4 and 6.5

## Appendix 2: Fraser Health Research Ethics Board Chair Terms of Reference

APPROVED: 2007 August 09

1<sup>st</sup> Revision: 2007 October 17

2<sup>nd</sup> Revision: 2011 December 13

**3<sup>rd</sup> Revision: 2015 December 09**

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The Chair(s) of the FHREB is responsible for carrying out the following activities and functions, and operates under the authority of the FH Policy “The Ethical Conduct of Research and Other Studies Involving Human Subjects”. The terms of reference for the FHREB co-Chairs, in addition, to those of the FHREB Members, are listed below.

1. Chair the full board meetings of the FHREB and ensure that the board meets the current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans and Health Canada requirements for quorum at each meeting.
2. Review and edit as required the comments submitted by board members following a meeting and prior to distribution to the investigators as requests for modification or deferral memoranda.
3. Review all applications for initial review, amendments and renewals of previously approved research, that qualify for expedited review under the minimal risk criteria and:
  - a) approve if all FHREB requirements have been met satisfactorily, or;
  - b) request that the investigator modify the study and/or respond to questions concerning the study prior to approval, or;
  - c) refer to the FHREB for review and approval.
4. Review investigators’ responses to requests for modifications that arise either from a full board meeting or from an initial expedited review of minimal risk studies, amendments and renewals and approve if all FHREB requirements have been met satisfactorily.
5. Develop guidance notes, policies and procedures for ethical review in collaboration with the board members and the Research Ethics and Regulatory Specialists, Research Ethics Board and the Executive Director, Department of Evaluation and Research Services, ex officio REB member.
6. Inform investigators of subject safety related issues that may arise during the course of a study and that require a response from the investigator. These may include, among others, following up serious adverse event reports, protocol violations and data safety monitoring board reports upon reviewing studies using interventions for which regulatory authorities (e.g. Health Canada, FDA) have issued safety alerts.
7. Review and respond to investigator’s reports of serious adverse events and protocol deviations.
8. Acknowledge close-out notices from investigators.

9. Participate in Health Canada inspections or NCEHR site visits as required.
10. Participate in investigations related to breach of compliance with Tri-Council policy, FH policy on “The Ethical Conduct of Research and other Studies Involving Human Subjects’ and the “FH Research Policy”.
11. Prepare the FHREB annual report in collaboration with the Executive Director, Department of Evaluation and Research Services.
12. Respond to investigator’s inquiries as appropriate.
13. [Approved 2015 December 09] Honoraria: REB co-chairs are paid \$850.00 per meeting. This also includes the expedited review of minimal risk applications which is conducted on a weekly basis.
  - i. Honoraria Paid to Non-FH Employees: Cheques for the honoraria are sent directly to the REB members, who are physicians or non-FH employees by FH Finance, at the address of their choice. There are no restrictions on the use of the honoraria by REB members who are non-FH employees or who are physicians.
  - ii. Honoraria Paid to FH Employees: Honoraria for REB members who are FH employees may be claimed by that member with the submission of the following documentation to the Research Ethics and Regulatory Specialists:
    - a. expense receipts,
    - b. as per FH “Travel and Business Expense” policy, the expense claim must be filled out on an “Employee Expense Report”, and,
    - c. a written justification for that expense made to the Executive Director, Department of Evaluation and Research Services who will approve the request.
10. A cheque requisition form is sent to FH Finance for reimbursement of the approved funds to that REB member.
11. Honoraria to REB members who are FH employees may be used for the type of expenses that FH employees would normally be able to claim and that are related to the work of the Research Ethics Board. This would normally include expenses related to education, conferences, and other out-of-pocket expenses. Other expenses may be considered upon presentation of an adequate written justification.
12. Any purchase of equipment and supplies that is approved by the Executive Director, Department of Evaluation and Research Services as per the FH Research Policy Section 4.3c.
13. Reference: Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. 2014. Articles 6.4 and 6.5
14. The Chair(s) of the FHREB is responsible for carrying out the following activities and functions, and operates under the authority of the FHA Policy “The Ethical Conduct of

Research and Other Studies Involving Human Subjects”. The terms of reference for the FHREB co-Chairs, in addition, to those of the FHREB Members, are listed below.

15. Chair the full board meetings of the FHREB and ensure that the board meets the current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans and Health Canada requirements for quorum at each meeting.
16. Review and edit as required the comments submitted by board members following a meeting and prior to distribution to the investigators as requests for modification or deferral memoranda.
17. Review all applications for initial review, amendments and renewals of previously approved research, that qualify for expedited review under the minimal risk criteria and:
  - a) approve if all FHREB requirements have been met satisfactorily, or;
  - b) request that the investigator modify the study and/or respond to questions concerning the study prior to approval, or;
  - c) refer to the FHREB for review and approval.
18. Review investigators’ responses to requests for modifications that arise either from a full board meeting or from an initial expedited review of minimal risk studies, amendments and renewals and approve if all FHREB requirements have been met satisfactorily.
19. Develop guidance notes, policies and procedures for ethical review in collaboration with the board members and the Research Ethics and Regulatory Specialists, Research Ethics Board and the Executive Director, Department of Evaluation and Research Services, ex officio REB member.
20. Inform investigators of subject safety related issues that may arise during the course of a study and that require a response from the investigator. These may include, among others, following up serious adverse event reports, protocol violations and data safety monitoring board reports upon reviewing studies using interventions for which regulatory authorities (e.g. Health Canada, FDA) have issued safety alerts.
21. Review and respond to investigator’s reports of serious adverse events and protocol deviations.
22. Acknowledge close-out notices from investigators.
23. Participate in Health Canada inspections or NCEHR site visits as required.
24. Participate in investigations related to breach of compliance with Tri-Council policy FHA policy on “The Ethical Conduct of Research and other Studies Involving Human Subjects’ and the “FH Research Policy”.
25. Prepare the FHREB annual report in collaboration with the Executive Director, Department of Evaluation and Research Services.
26. Respond to investigator’s inquiries as appropriate.
27. Honoraria: REB co-chairs are paid \$850.00 per meeting. This also includes the expedited review of minimal risk applications which is conducted on a weekly basis.
  - iv. Honoraria Paid to Non-FHA Employees: Cheques for the honoraria are sent directly to the REB members, who are physicians or non-FH employees by FH Finance, at



the address of their choice. There are no restrictions on the use of the honoraria by REB members who are non-FH employees or who are physicians.

- v. Honoraria Paid to FHA Employees: Honoraria for REB members who are FH employees may be claimed by that member with the submission of the following documentation to the Research Ethics Research Ethics and Regulatory Specialists:
  - a. expense receipts,
  - b. as per FHA "Travel and Business Expense" policy, the expense claim must be filled out on an "Employee Expense Report", and,
  - c. a written justification for that expense made to the Executive Director, Department of Evaluation and Research Services who will approve the request.

A cheque requisition form is sent to FHA Finance for reimbursement of the approved funds to that REB member.

Honoraria to REB members who are FHA employees may be used for the type of expenses that FHA employees would normally be able to claim and that are related to the work of the Research Ethics Board. This would normally include expenses related to education, conferences, and other out-of-pocket expenses. Other expenses may be considered upon presentation of an adequate written justification.

Any purchase of equipment and supplies that is approved by the Executive Director, Department of Evaluation and Research Services as per the FHA Research Policy Section 4.3c.

Reference: Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada. Tri-Council Policy for Ethical Policy Statement: Ethical Conduct for Research Involving Humans. 2010. Articles 6.4 and 6.5

## Appendix 3: Potential Conflict of Interest Declaration for FHREB Members

Please complete the sections below to provide information to the FHREB Co-Chairs and Executive Director of Research Services about circumstances concerning **you and/or your partner(s) and/or immediate family members (including children, whether living in the household or not)** that could lead to a conflict of interest with the business of Fraser Health Research Ethics Board (FHREB). Include any relevant details from the past two years of your life, including your current situation. Exact details of remuneration are not required.

<b>1. Personal Details:</b>	
Surname:	Postal Address:
Given Names:	
Hospital Department (if applicable):	
Hospital Division (if applicable):	Phone Number:
Citizenship: <input type="checkbox"/> Canadian	Fax Number:
<input type="checkbox"/> Landed Immigrant	E-mail Address:
<input type="checkbox"/> Other:	
<b>2. Research Support:</b> <input type="checkbox"/> Yes <input type="checkbox"/> No	
Provide brief details, including names of sponsors and types of support (e.g. salary, grants, equipment, fees).	
✦ Self:	
✦ Partner and/or Immediate Family members:	
<b>3. Consultancy Activities:</b> <input type="checkbox"/> Yes <input type="checkbox"/> No	
Provide brief details, including name(s) of companies who have utilized your services and amount of time spent on consulting.	
✦ Self:	

✖ Partner and/or Immediate Family members:

**4. Fees or honoraria for writing research proposals or publications:**  Yes  No

Provide details about the organization from which you received the fees.

✖ Self:

✖ Partner and/or Immediate Family members:

**5. Speaker fees and/or educational awards/honoraria:**  Yes  No

Provide details about the organization from which you received the fees.

✖ Self:

✖ Partner and/or Immediate Family members:

**6. Travel assistance to attend conferences or meetings:**  Yes  No

Provide details about the organization from which you received the assistance.

✖ Self:

✖ Partner and/or Immediate Family members:

**7. Membership(s) on Research Professional Boards or Institutional Boards (for profit and not-for-profit):**  Yes  No List memberships.

Provide details about the organization from which you received the fees.

✖ Self:

✘ Partner and/or Immediate Family members:

**8. Ownership of stock, stock options, or other equity holdings:**  Yes  No

No declaration is expected for managed or mutual funds.

✘ Self:

✘ Partner and/or Immediate Family members:

**9. Any additional financial or other relationship** which could be a potential conflict of interest (such as patent rights, intellectual property rights):  Yes  No

✘ Self:

✘ Partner and/or Immediate Family members:

**10. I understand that it is my responsibility to indicate to the FHREB Co-Chairs when I have a conflict of interest with an application coming before the committee.**

**Signature:** \_\_\_\_\_

**Date:**

**Printed Name:**

## Appendix 4: Revisions to FHREB Documentation

<b>Documents</b>	<b>Most Recent Version</b>
Application for Initial Ethical Review Form revised to incorporate Privacy data access agreement	Version 12: 2018 March 26
Fraser Health Institutional Approval Application Form for Harmonized Studies	(New) 2019 February 25
Fraser Health Institutional Approval Application Form for Harmonized Clinical Trials	(New) 2019 March 01
Application for Initial Ethical Review Form_Affiliated Researchers	Decommissioned
Application for Initial Ethical Review Form_for RISE Studies	Decommissioned
Researcher Response Form	Version 14: 2018 November 25
Integrated Post-approval Application Form for Amendments, Renewals, Close-outs, Acknowledgements of Previously Approved Research	Version 6: 2018 March 26
Change of Principal Investigator Form	Version 5: 2018 November 26
Local Serious Adverse Event Report Form	Version 8: 2014 March 10
Protocol Deviation Form	Version 6: 2014 March 10
Guidance Notes for New Applications for Ethical Review	Version 29: 2019 January 15
Guidance Notes for Amendment	2018 November 27
Guidance Notes for Renewal	2018 November 27
Guidance Notes for Close-Outs	(New) 2018 November 27
Guidance Notes for Reporting Unanticipated Problems to the FHREB	Version 2.0: 2018 November 27
Protocol Deviation Guidance Notes	Version 2.0: 2018 November 27
BC Common Clinical Informed Consent Form Template	2019 February 07
Consent Form Template For Optional Research	(New) 2019 February 06
Consent Form Template For Qualitative Research	(New) 2019 February 06
Consent Form Template For Prospective Secondary Data Collection Only	2019 February 06
Temporary Optional Consent Form	Decommissioned
Assent Form Template	2019 February 06
Consent Form Template For Surveys	2019 February 06
Pregnant Partner Data Release Consent Form Template	(New) 2019 February 06
Consent Form Checklist	Decommissioned
Consent to Contact and Use Data Template	Decommissioned
Consent to Contact for Future Participation in Research	Decommissioned
Consent to Review Records and Contact Template	Decommissioned
Consent to Review Records to Determine Eligibility	Decommissioned
Non-clinical (i.e. survey, focus groups, observational) Consent Form Template for Patients	Decommissioned

Non-clinical (i.e. survey, focus groups) Consent Form Template for Staff	Decommissioned
Consent Form Template For Case Reports	2019 February 06
Department Agreement for Providing Research-related Services Form	Version 31: 2019 February 08