

Fraser Health Research Ethics Board



Annual Report

April 1, 2017
to
March 31, 2018

FRASER HEALTH RESEARCH ETHICS BOARD ANNUAL REPORT

APRIL 1ST 2017 TO MARCH 31ST 2018

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FRASER HEALTH RESEARCH ETHICS BOARD

ANNUAL REPORT

APRIL 1ST, 2017 TO MARCH 31ST, 2018

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 2017-2018 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. With regret, the board accepted the resignation of MaryEllen Gillan, who had been a community member for 7 years. In addition to ensuring that scientific information in participant consent forms was made understandable for a lay person, MaryEllen also brought with her knowledge of Indigenous peoples as part of the Canadian Metis community. The FHREB is very grateful for her long years of thoughtful service to the Fraser Health research community. In her place, Bonnie MacKenzie was recruited. With previous experience as a community representative on other research ethics boards, Bonnie has quickly assumed the responsibilities of this role. In addition, Dr. Dennis Orton, PhD resigned from the board as a full time member, agreeing to be available as an alternate member or for when specialized laboratory science expertise is

required. Michelle Tsai, a therapist and researcher with Fraser Health, joined the board in 2017, to provide expertise in mental health and substance use. Tim Leung, PharmD, became the newest board member from Pharmacy. Tim brings with him pharmacological expertise that is essential to the review of clinical drug protocols and drug safety information. The board was very pleased to welcome Michelle, Bonnie and Tim as its newest members.

Table 1: 2017-2018 FHREB Membership List

| | VOTING MEMBER NAME FIRST LAST | HIGHEST DEGREES EARNED | PRIMARY SCIENTIFIC OR NONSCIENTIFIC SPECIALTY | ‡TERM | AFFILIATION WITH INSTITUTION |
|--|--|---------------------------------------|--|--|---|
| 1 | *Dr. Stephen Pearce Male / Canadian Citizen | MD, FRCPC | Cardiology | June 26, 2017 to June 26, 2018 | 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 | Ethics | January 31, 2018 to January 31, 2019 | No |
| 4 | ** Anu K. Sandhu Female/Canadian Citizen | LLB | Law | June 03, 2015 to June 03, 2018 | 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 | June 23, 2015 to June 23, 2018 | Yes |
| 10 | **Dennis Orton Male / Canadian Citizen | PhD | Clinical Biochemistry & Pathology | September 01, 2017 to September 01, 2018 | Yes |
| 11 | Michelle Tsai Female / Canadian Citizen | MA | Counselling Psychology | October 03, 2017 to October 03, 2020 | Yes |
| 12 | Bonnie MacKenzie Female / Canadian Citizen | BA | Community Member | January 31, 2018 to January 31, 2021 | No |
| 13 | Tim Leung Male / Canadian Citizen | PharmD | Pharmacy | March 12, 2018 to March 12, 2012 | Yes |
| * Co-chair ** Alternate *** non-voting member ‡ Date of Appointment Letter Ex officio: Susan Chunick, 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)¹. In addition, the FHREB complies with Health Canada regulations and guidelines concerning the ethical review of clinical drug², device³ and natural health product⁴ 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 Administration⁵. 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.⁶ 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 2014 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.

¹ Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada. Tri-council Policy December 2010 and amendments (December 2014).

<http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>

² September 1, 2001. Regulations Amending the Food and Drug Act Regulations (1024 - Clinical trials) at http://www.hc-sc.gc.ca/dhp-mpps/prodpharma/applic-demande/guide-ld/clin/cta_documents-eng.php

³ Part 3 of the Medical Devices Regulations at <http://www.hc-sc.gc.ca/dhp-mpps/md-im/index-eng.php>

⁴ Part 4 of the Natural Health Product Regulations at <http://www.hc-sc.gc.ca/dhp-mpps/prodnatur/index-eng.php>

⁵ 45CFR and 21CFR at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

and <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

⁶ Fraser Health Authority. Revised January 2014. The Ethical Conduct of Research and Other Studies Involving Human Participants http://fhpulse/clinical_resources/clinical_policy_office/Lists/CDST%20Library/DispForm.aspx?ID=778

2.4 FHREB Education

The annual education session for the FHREB was held on March 03, 2018 for this fiscal year. This session included a presentation by Dr. Matthew Heinz, the Vice Provost of Royal Roads University, on the Canadian Professional Association for Transgender Health (CPATH) Research Committee's ethical guidelines for research involving trans people. The session also included a presentation by Dr. Hana Sroka (Senior Genetic Counsellor, Clinical Genomics Program, GeneDx Laboratory; Case-Based Tutor for UBC, Faculty of Medicine; Lead of Prenatal Community of Practice, Canadian Association of Genetic Counsellors) on the topic of Bill S201 and the intersection of genetics, ethics and law.

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 TO FRASER HEALTH RESEARCHERS

3.1 FHREB Standard Requirements

In order to ensure that the FHREB Guidance Notes, application forms and consent form templates meet current ethical standards and best practices for the disclosure of information by researchers, these documents are reviewed and revised on an ongoing basis. See Appendix 4 for the revision status of each document. All changes were communicated to the Fraser Health research community via posting to the health authority's Department of Evaluation and Research Services web site or in direct email communication to clinical trial researchers when a need to ensure regulatory compliance was involved.

3.2 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 reviewed 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.

3.3 Standard Operating Procedures

A comprehensive review and revision of the standard operating procedures (SOPs) for the administration of the research ethics process was undertaken in 2017-2018 in order to ensure that these SOPs are consistent with the national standards developed by the Canadian Association of Research Ethics Boards.

3.4 Research Quality Improvement Program

No research studies were inspected in the 2017-2018 fiscal year.

3.5 Research Ethics Education

Five 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.

3.6 Research Ethics Web Site

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/health-professionals/research-and-evaluation/find-resources/forms-guidance-notes-templates/forms-guidance-notes-templates>.

A feature of this web site is the Research Study Database at <https://www.fraserhealth.ca/health-professionals/research-and-evaluation/getting-started/research-study-database/research-study-database>. Comprehensive information on individual studies including their FHREB approval status is available from this database.

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 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 Coordinator (Sara O'Shaughnessy) and one part-time Coordinator (Sarah Flann). The FHREB Coordinators 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 Coordinator and in congruence with the TCPS2 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 Coordinator);
- 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 (addition of study site, submission of new recruitment material, consent form language, i.e. 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 Coordinators represented the FHREB on the Research Ethics BC Harmonization initiative Advisory Committee. The FHREB Coordinators 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 258 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. The funding provided by the Michael Smith Foundation for Health Research (MSFHR) to support the Harmonization Initiative completed at the end of the 2016-2017 fiscal year with the expectation that research ethics harmonization in BC will be moved from an initiative to a sustained entity rebranded as Research Ethics BC (REBC).

The Fraser Health REB Office contributed input 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 October 01, 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 Fraser Health Research Ethics Coordinators participated in a provincial working group to revise the BC Common Informed Consent Form Template. The template is currently under review by REBC partner institutional REBs for approval.

The Fraser Health Research Ethics Coordinators have also actively engaged with REBC partners to develop a framework for the harmonized review of retrospective chart review studies. Retrospective chart review studies were previously excluded from harmonized review. Currently REBC partner members are piloting harmonized chart review with a formal rollout expected to occur in the 2018-2019 fiscal year.

Dr. O'Shaughnessy initiated the creation of a provincial working group to develop a harmonized clinical trials ethical review framework from non-industry sponsored multi-jurisdictional clinical trials. This work is ongoing.

During the 2017-2018 fiscal year, the FHREB received 51 requests for harmonized initial ethical reviews. The FHREB served as board of record for 19 submissions and REBC partner institutions served as board of record for 32 submissions. This is a 59% increase from the 32 requests for harmonized initial ethical review received in the 2016-2017 fiscal year.

Fraser Health has also entered into academic affiliation agreements with 22 new affiliated investigators expanding their research into the Fraser Health Region. This is a 175% increase from the 8 new affiliated investigators signed into affiliation agreements during the 2016-2017 fiscal year.

In addition, the FHREB continues to be the board of record for initial and ongoing approval of research studies conducted by the University of British Columbia family practice residents who are required to complete a research study during their residency in Fraser Health.

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 worker relationships.

4.4 Optimizing Document Management and Workflow

The FHREB office has worked 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. Key outputs from this project include:

1. redesign of the initial application form for visual clarity;
2. alignment of the fields in the Access database with the initial application form to ensure consistency and enable population of data from the form directly into the database; and,
3. creation of automatic reminders to principal investigators of the one year requirement for annual renewal.

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 with new studies submit an initial application for ethical review 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, 102 requests for initial ethical review were received for review by the FHREB, representing a 4% decrease from the previous fiscal year. However, the overall demand for review of 660 applications of all types increased by 28% compared to the 2016-2017 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=660
April 1, 2017 to March 31, 2018**

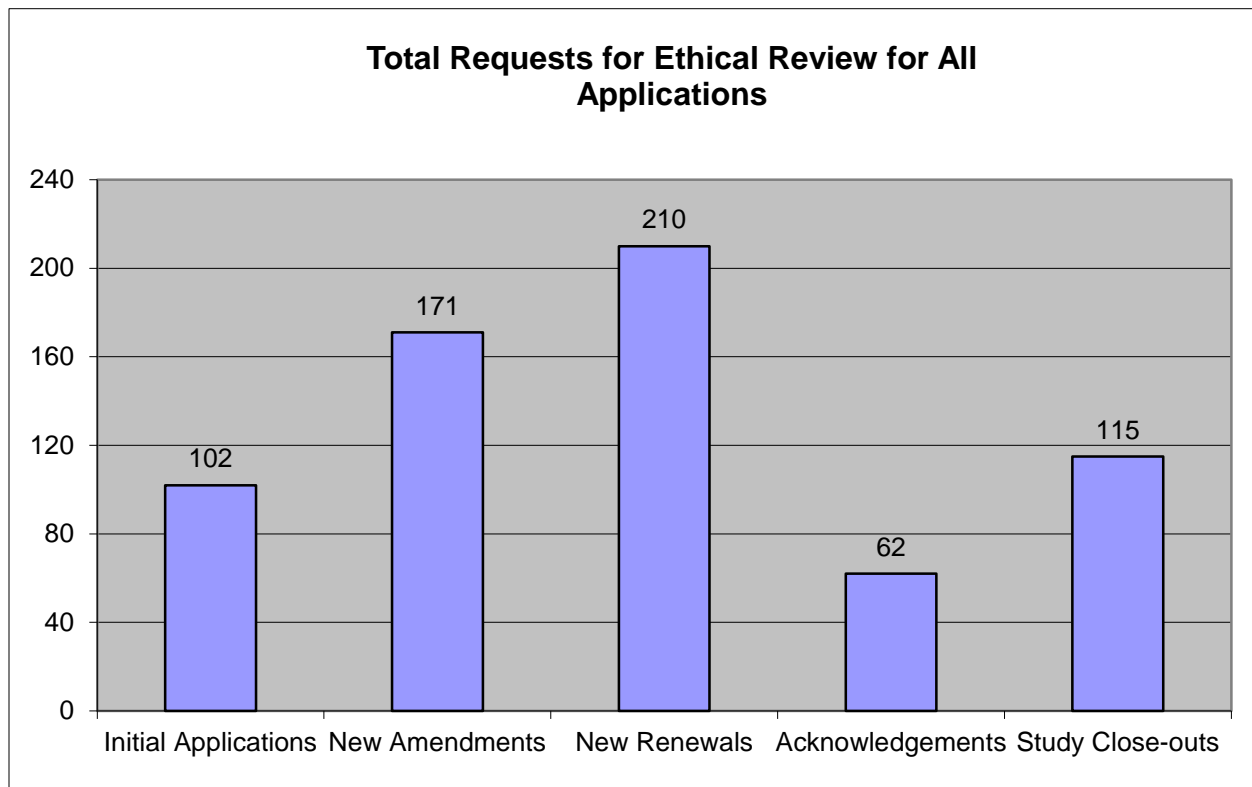


Figure 2: Total Number of Requests for Ethical Review by Fiscal Year April 1, 2013 to March 31, 2018

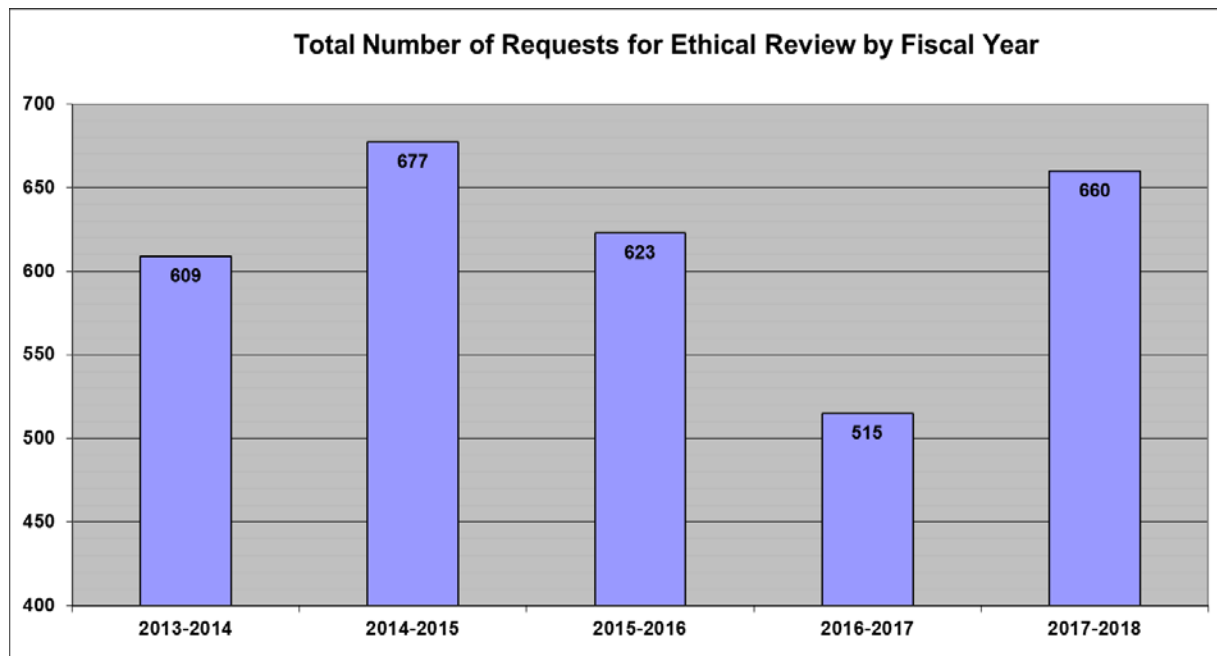


Table 2: Type of Requests for Ethical Review by Fiscal Year from 2012-2017

| Type of Application | 2013-2014 | 2014-2015 | 2015-2016 | 2016-2017 | 2017-2018 |
|-------------------------|-----------|-----------|-----------|-----------|-----------|
| Initial | 131 | 145 | 132 | 106 | 102 |
| Amendment | 137 | 169 | 147 | 115 | 170 |
| Renewal | 149 | 185 | 192 | 173 | 210 |
| Close-out | 128 | 105 | 83 | 53 | 115 |
| Acknowledgements | 64 | 73 | 69 | 68 | 62 |

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 Coordinators to prepare all pre-review material required for the board's review of each study.

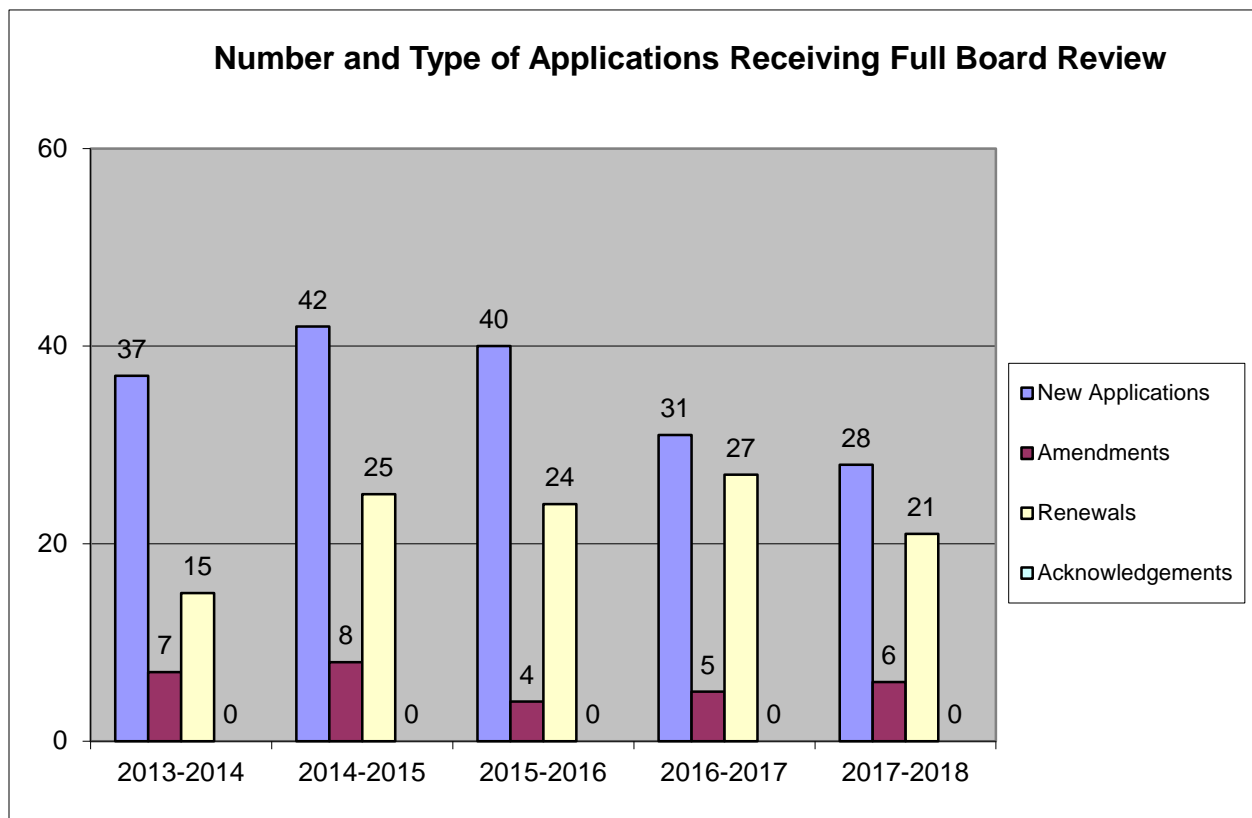
Workload varies from demand data because applications received late in the fiscal year may be reviewed in the following fiscal year. The FHREB reviewed a total of 656 applications (including acknowledgements of serious adverse event reports, protocol deviations, data safety monitoring board reports) for this fiscal year. This reflects a 25% increase compared to the review of 524 applications for the prior fiscal year.

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 Coordinators as of 2015 for review from 2013 to 2018.

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.

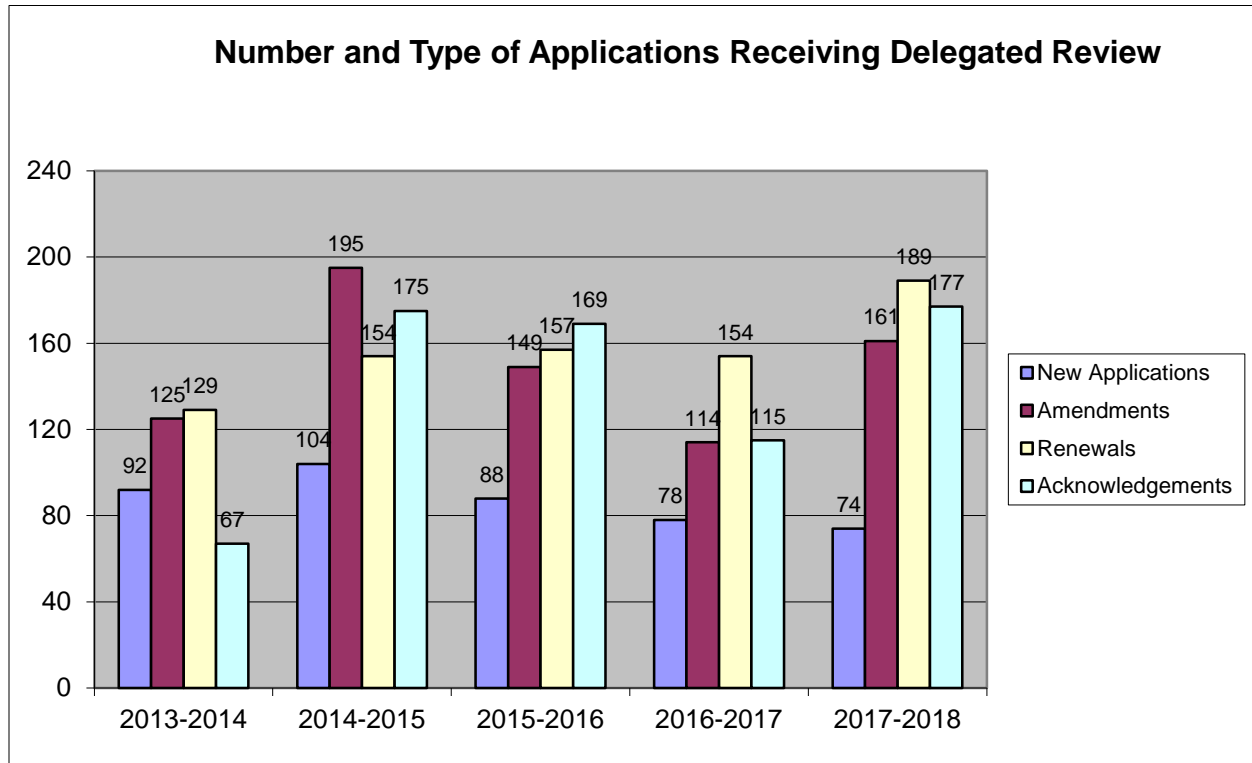
Note that this data does not include subsequent modifications arising from either a delegated or full board review of initial or amendment applications that were conducted in the prior fiscal year. For this workload data, please see 5.2.2.

Figure 3: Number and Type of Applications Receiving Full Board Review April 1, 2017 to March 31, 2018



**Figure 4: Number and Type of Applications Receiving Delegated Review
April 1, 2013 to March 31, 2018**

(n.b. Please note that acknowledgements include the review of close-outs. This was not included in the data for 2013-2014).



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...”.⁷ 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

⁷ Health Canada, Health Products and Food Branch: Clinical Safety Data Management Definitions and Standards for Expedited Reporting, ICH Topic E2A <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/clinical-trials/background.html>

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".⁸ Seven 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 2017-2018 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 Coordinators.

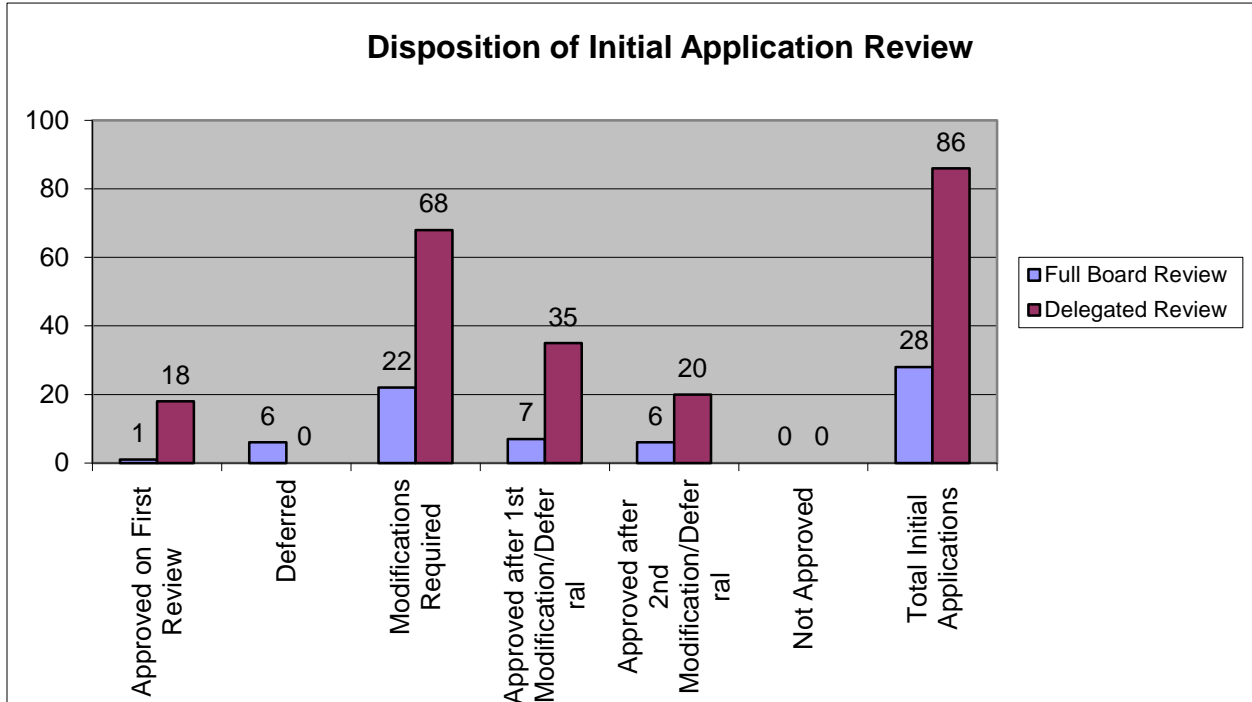
All principal investigators are expected to reply to the request for either modification or deferral within six months of the FHREB's decision, otherwise the study will be closed by the FHREB Coordinator and the principal investigator notified of that decision. The principal investigator may submit the 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 six 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.

⁸ Fraser Health: Guidance Note for Submitting Protocol deviations to the FHREB, 2008 11 18.
<http://research.fraserhealth.ca/approvals-&-ethics/forms-and-guidance-notes/>

Figure 5: Disposition of Review of Initial Applications by Full Board and Delegated Review
April 1, 2017 to March 31, 2018



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 2017-2018 fiscal year are reported.

Figure 6: Disposition of Review of Amendment Applications by Full Board and Delegated Review
April 1, 2017 to March 31, 2018

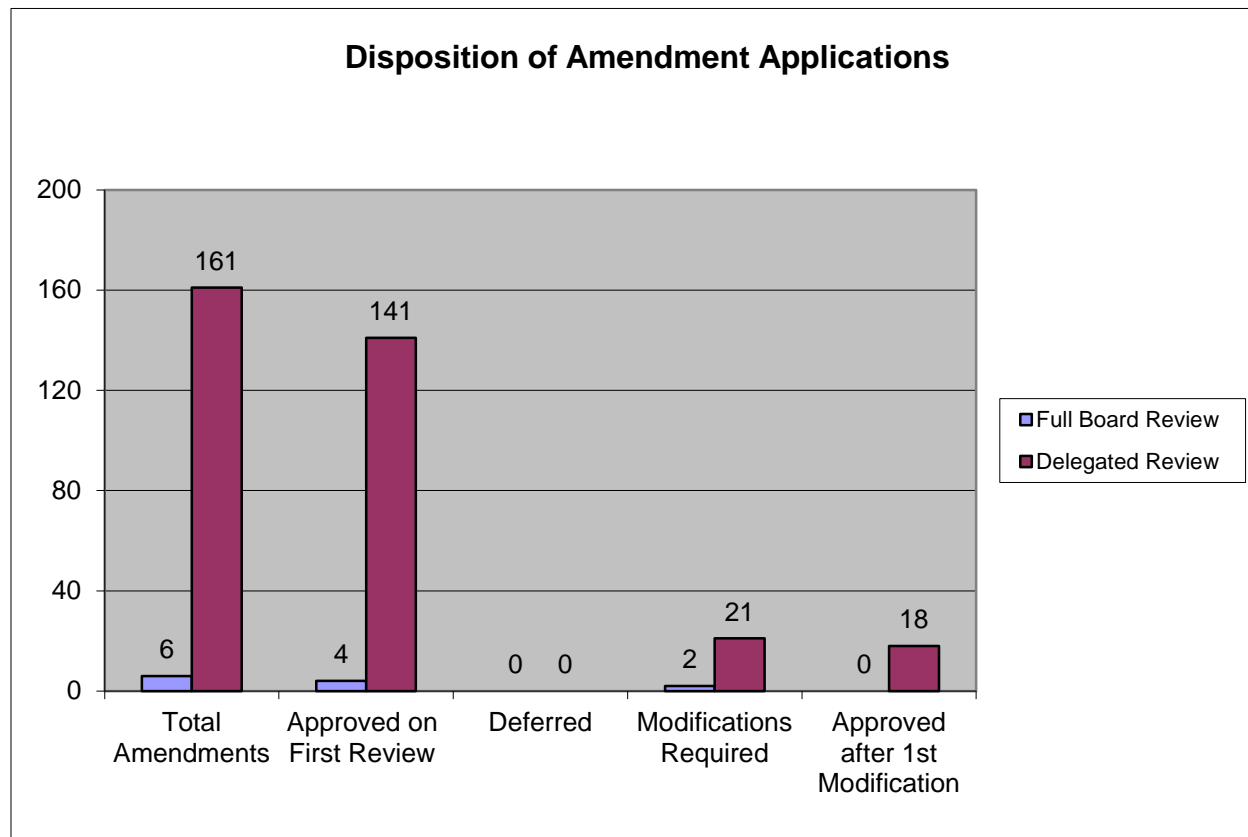
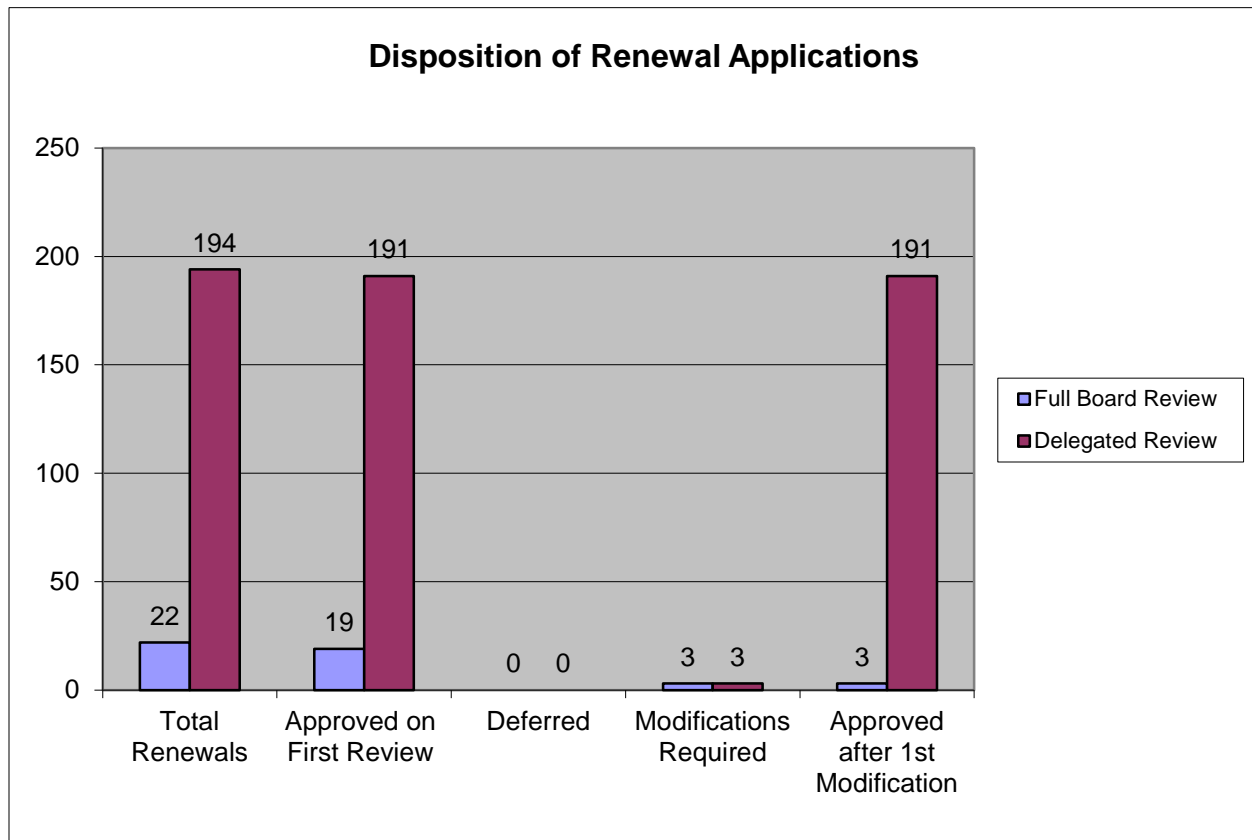


Figure 7: Disposition of Review of Renewal Applications by Full Board and Delegated Review Received from April 1, 2017 to March 31, 2018



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-eight studies (i.e. 22%) were renewed outside of the date of expiry which is one year from the initial date of approval or renewal. It is expected that this statistic will decrease with the automatic renewal reminders that are now being sent to researchers within a month of approval expiry.

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 Coordinator 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 58 days, with 16 days for delegated review. A

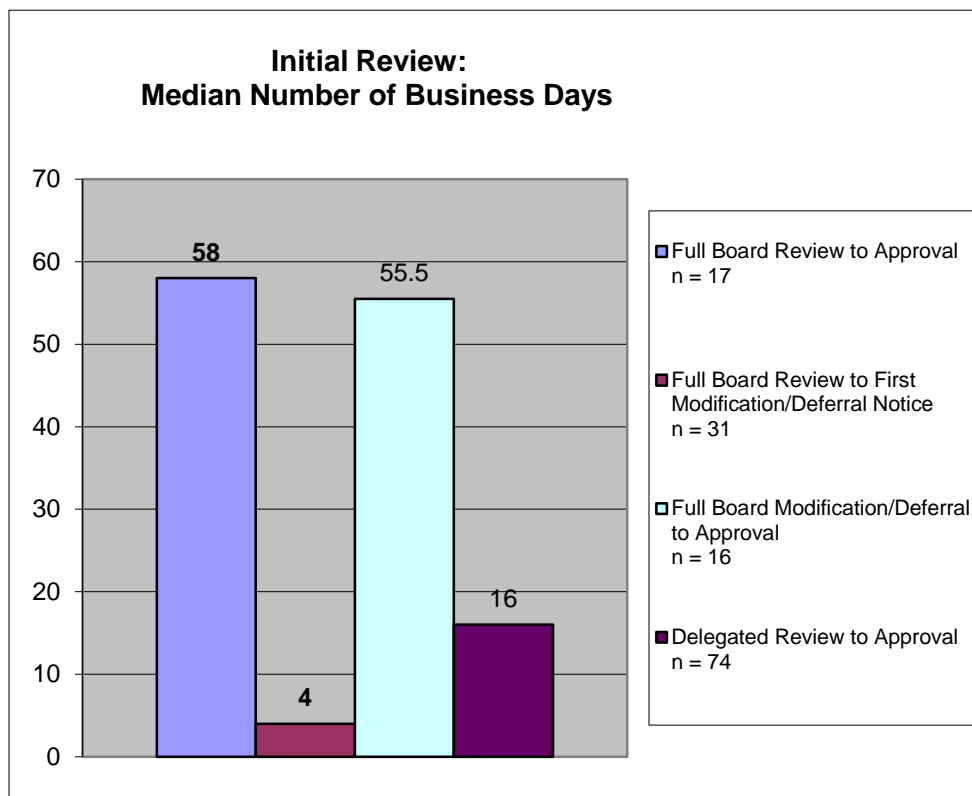
portion of this time is attributed to the length of time it takes for the principal investigator to respond to the modification or deferral notice. It is important to note that this may also reflect the time it takes for an industry or academic sponsor to review and accept the required FHREB changes 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 FHREB Coordinator 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.

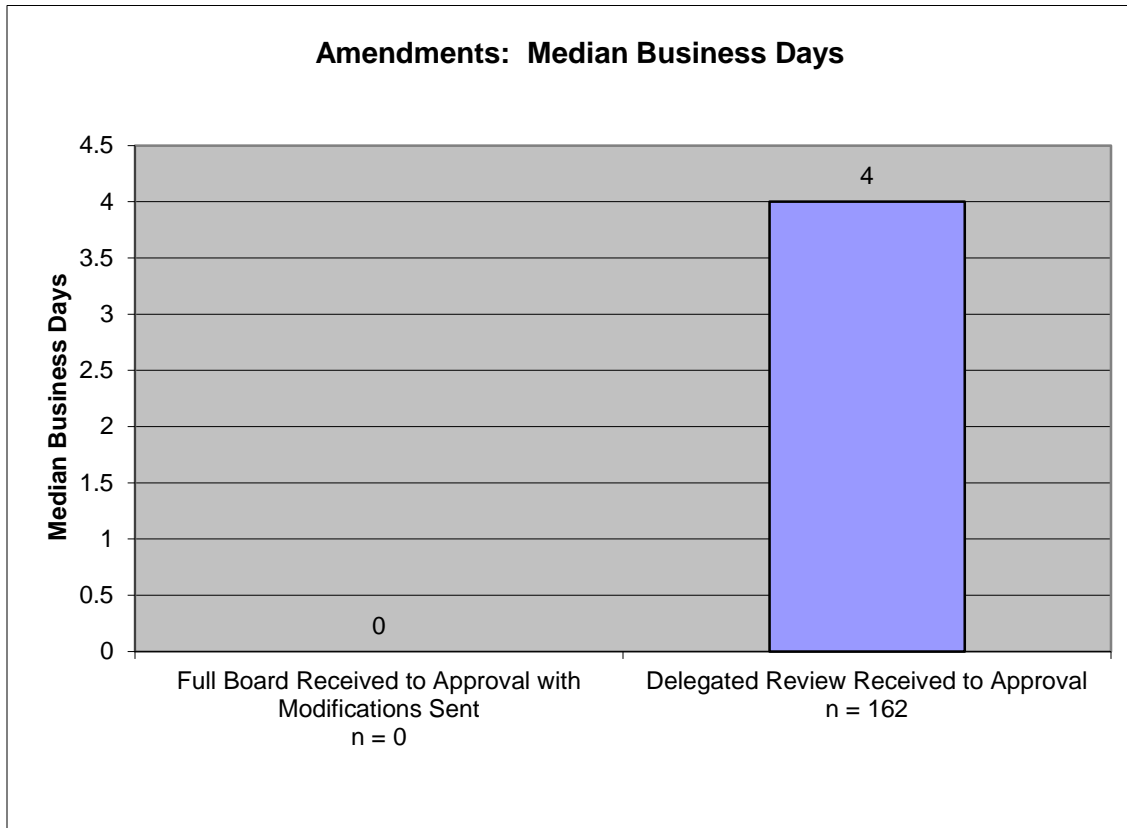
All timelines in the following figures are reported in median number of business days. Studies that were reviewed but did not receive final approval in this fiscal year are not included.

**Figure 8: Initial Review: Median Number of Business Days for Full Board and Delegated Review
April 1, 2017 to March 31, 2018**



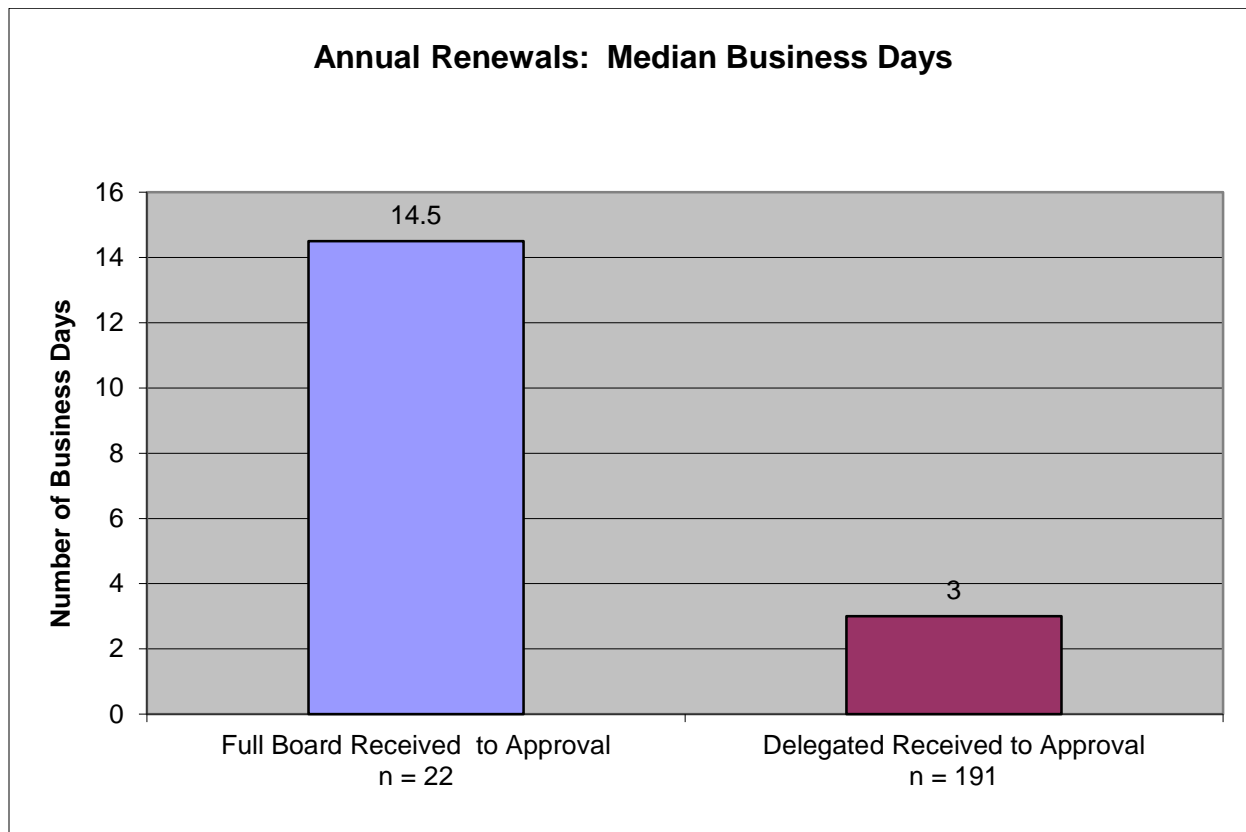
The timeline for amendment approvals is shown in Figure 9. The median number of business days for amendments for delegated review received to approval is four business days (n = 162). There were no full board amendments in the 2017-2018 fiscal year.

Figure 9: Amendments: Median Number of Business Days for Full Board and Delegated Review
April 1, 2017 to March 31, 2018



The timeline for renewals is shown in Figure 10 illustrates the timelines for review of renewal applications. No renewal applications reviewed at full board received modification requests.

**Figure 10: Annual Renewals: Median Number of Days from Date of Full Board and Delegated Review to Approval
April 1, 2017 to March 31, 2018**



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 no research-related privacy breaches reported to the Fraser Health Privacy Office and the FHREB in the 2017-2018 fiscal year.

6.3 Participant Complaints

There was one complaint from the parent of a participant in a study concerning the handling of their child's blood samples and the consenting procedures. Upon investigation by the REB office, it was determined that the participant had not been enrolled at the Fraser Health site, and no research procedures for this participant had taken place at Fraser Health. The participant had been enrolled at the main study principal investigator's site at a different

health authority. Due to the complainant's request that the FHREB not communicate with any other parties, the REB office was unable to provide a full response regarding the location of the samples. However, the board did note that this complaint arose in part due to a therapeutic misconception in which the participant's parents believed the principal investigator to be a medical doctor rather the scientist. As a result, the board agreed to adopt a requirement that principal investigators who are not medical doctors use the designation "PhD" rather than "Dr." on consent forms.

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.

- a. 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.
 - % 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: 78%
- b. Serious Adverse Events.
 - # of Local Serious Adverse Events: 2
- c. Participant Complaints, Appeals and Privacy Breaches: There was one participant complaint 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.

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 the BC Ethics Harmonization Initiative as clarification of the legislation is imperative for the review of multi-jurisdictional research.

The workload of the FHREB and the FHREB Coordinators 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 FHREB Coordinators undertake between their counterpart REB administrators for multi-jurisdictional research. Maintaining efficiency of review for our researchers, including those academic researchers that are affiliated with Fraser Health, is important with respect to customer service.

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 2017-2018 annual report at its September 12th 2018 meeting.

Respectfully submitted,



Dr. Stephen Pearce
FHREB co-Chair



Professor Lindsay Meredith
FHREB co-Chair

APPENDIX 1

TERMS OF REFERENCE

FRASER HEALTH RESEARCH ETHICS BOARD MEMBERS

APPROVED: 2007 August 09

1st revision: 2007 October 17

2nd revision: 2011 December 13

3rd revision: 2015 December 09

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 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 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 Co-ordinator:
 - 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 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 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 for Ethical Policy Statement: Ethical Conduct for Research Involving Humans. 2010. Articles 6.4 and 6.5

APPENDIX 2

TERMS OF REFERENCE

FRASER HEALTH RESEARCH ETHICS BOARD CHAIR

APPROVED: 2007 August 09

1st Revision: 2007 October 17

2nd Revision: 2011 December 13

3rd Revision: 2015 December 09

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 Coordinator, Research Ethics Board and the 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 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.
 - iii. **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.
 - iv. **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 Co-ordinator:
 - 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 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 Director, Department of Evaluation and Research Services as per 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 for Ethical Policy Statement: Ethical Conduct for Research Involving Humans. 2010. Articles 6.4 and 6.5

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.

14. 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.
15. 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.
16. Review all applications for initial review, amendments and renewals of previously approved research, that qualify for expedited review under the minimal risk criteria and:
 - d) approve if all FHREB requirements have been met satisfactorily, or;
 - e) request that the investigator modify the study and/or respond to questions concerning the study prior to approval, or;
 - f) refer to the FHREB for review and approval.
17. 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.
18. Develop guidance notes, policies and procedures for ethical review in collaboration with the board members and the Coordinator, Research Ethics Board and the Director, Department of Evaluation and Research Services, ex officio REB member.
19. 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.
20. Review and respond to investigator's reports of serious adverse events and protocol deviations.
21. Acknowledge close-out notices from investigators.
22. Participate in Health Canada inspections or NCEHR site visits as required.
23. 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".
24. Prepare the FHREB annual report in collaboration with the Director, Department of Evaluation and Research Services.
25. Respond to investigator's inquiries as appropriate.
26. **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.
 - v. **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.

- vi. **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 Co-ordinator:
- 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 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 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 FRASER HEALTH RESEARCH ETHICS BOARD MEMBERS**

Please complete the sections below to provide information to the FHREB Co-Chairs and 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.

| |
|---|
| <p>1. Personal Details:</p> <p>Surname: _____ Postal Address: _____ Given Names: _____ Hospital Department (if applicable): _____ Hospital Division (if applicable): _____ Citizenship: <input type="checkbox"/> Canadian <input type="checkbox"/> Landed Immigrant <input type="checkbox"/> Other: _____ Phone Number: _____ Fax Number: _____ E-mail Address: _____</p> |
| <p>2. Research Support: <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:</p> |
| <p>3. Consultancy Activities: <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:</p> |
| <p>4. Fees or honoraria for writing research proposals or publications: <input type="checkbox"/> Yes <input type="checkbox"/> No Provide details about the organization from which you received the fees. ✖ Self: ✖ Partner and/or Immediate Family members:</p> |
| <p>5. Speaker fees and/or educational awards/honoraria: <input type="checkbox"/> Yes <input type="checkbox"/> No Provide details about the organization from which you received the fees. ✖ Self:</p> |

✘ 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

| Documents | Most Recent Version # Date |
|--|--|
| Application for Initial Ethical Review Form revised to incorporate Privacy data access agreement | Final: 2018 March 26 Revision: 2017 March 14 |
| Application for Initial Ethical Review Form_Affiliated Researchers | Final: 2017 August 21 Revision: 2017 August 21 |
| Application for Initial Ethical Review Form_for RISE Studies | Final: 2017 August 21 Revision: 2017 August 21 |
| Researcher Response Form | Version 14: 2016 05 06 |
| Integrated Post-approval Application Form for Amendments, Renewals, Close-outs, Acknowledgements of Previously Approved Research | Final: 2018 March 26 Revision: 2018 February 26 |
| Change of Principal Investigator Form | Version 4: 2015 May 06 |
| Guidance Notes for New Applications for Ethical Review | Final: Version 27: 2017 March 13 Revision: Version 26: 2016 November 17 |
| Guidance Notes for Amendment | Version: 2016 November 17 |
| Guidance Notes for Renewal | Version: 2016 November 17 |
| Guidance Notes for Reporting Unanticipated Problems to the FHREB | Version: 2011 December 15 |
| BC Common Clinical Informed Consent Form Template | Version: 2015 October |
| Temporary Optional Consent Form | Version #6: 2012 03 28 |
| FHREB Assent Form Template | Final: 2017 October 31 |
| Consent Form Checklist | Version: 2012 March 27 |
| Consent to Contact and Use Data Template | Version: 2011 October 13 |
| Consent to Contact for Future Participation in Research | Version #2: 2011 October 13 |
| Consent to Review Records and Contact Template | Version #2: 2011 October 13 |
| Consent to Review Records to Determine Eligibility | Final: 2017 October 31 |
| Non-clinical (i.e. survey, focus groups, observational) Consent Form Template for Patients | Version #5: 2016 January 25 |
| Non-clinical (i.e. survey, focus groups) Consent Form Template for Staff | Version #5: 2016 January 25 |
| Survey Template | Final: 2017 February 04 |
| Department Agreement for Providing Research-related Services Form | Final: 2018 March 28 Revision: 2018 March 28 |