

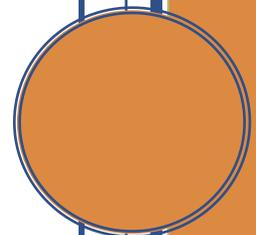


Interior Health
Every person matters

RESEARCH ETHICS BOARD ANNUAL REPORT

April 1, 2017 – March 31, 2018

Dorothy Herbert, Coordinator, IH Research Ethics Board



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A. Executive Summary

This report highlights the activities of the Interior Health Research Ethics Board (REB) in 2017-18. The REB is supported by the Research Ethics Office (REO), so highlights of the REO's work are included. In addition to supporting ethical review of research, the REO tracks data to help the organization better understand what sort of research is occurring, where it is occurring, and who is leading it.

In 2017-18, the REB received 87 new studies for review. The three-year moving average is now 89 new studies per year, a 58% increase from just three years ago. The majority of research initiated in Interior Health is locally driven, with over 60% of all new research initiated by IH or our academic partners located within the IH catchment. IH is also a generous supporter of student research, with 35% of new studies being led by students. Many of these projects are supported in-kind by IH; in return, IH receives information it employs to support the delivery of evidence-informed care to patients, clients and residents. Though the REO does not specifically track the alignment of research studies with the 5 Key Strategies, a review undertaken in 2016-17 and an informal analysis conducted in 2017-18 suggest that nearly half of all research submitted to the REB supports at least one of the Key Strategies.

The REB currently maintains oversight of 170 active research studies, a jump of 60% in the past 3 years. Much of this work is done on behalf of the REB by the Research Ethics Office (REO), but the REB still meets monthly to review interventional and higher-risk research studies. The membership of the board can change over time but never varies from the core commitment to provide expertise in the relevant scientific, legal, and community perspectives required for ethical review of research. To accommodate the increase in the number of studies under its purview, REB membership has grown from 10 standing and 4 substitute members in the fiscal year 2017-2018 to 13 standing and 6 substitute members currently.

In addition to providing leadership and support for research ethics reviews, the Research Ethics Office (REO) provides consultation services on matters pertaining to research and ethics, provides leadership in research policy development, and provides relevant educational opportunities and resources to REB members, IH staff, and researchers. In 2015-16, the need for more research ethics-related education was identified and the REO delivered. Research ethics education opportunities were offered more frequently and to a wider variety of audiences, both internal and external to IH, than ever before.

In addition to continuing with this educational outreach, in 2018-19 the REO will participate in the implementation of a Provincial Research Ethics Platform (PREP). PREP promises to change the research landscape in BC in similar positive ways that the BC Ethics Harmonization Initiative (BCEHI)¹ has done.

B. Introduction

The Interior Health Research Ethics Board (REB) provides independent ethical review of research that involves human participants and is conducted within the jurisdiction of IH. This includes research that: occurs in an IH facility; involves an IH staff member, physician, or student as a researcher; or involves IH patients, clients, residents, staff, physicians, volunteers, students, or their information as participants. The REB commenced operations in November 2005, replacing three site-specific Research Review Committees, and making a REB review accessible to every site, employee, and physician throughout the health authority.

The REB abides by the national standard for research ethics review, the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2014)*, commonly known as the TCPS2. In addition, the REB observes applicable Health Canada and US Food and Drug Administration (FDA) regulations, privacy legislation, and institutional policy. The REB works to provide thoughtful interpretation of these standards in order to promote the highest ethical conduct of research involving human participants.

C. Research Ethics Reviews 2017-18

1. New Research Ethics Applications

In 2017-18, the REB received 87 new applications for ethical review. This number is well above the ten-year moving average of 67 per year. This is the third consecutive year for a higher-than-average number; the factors influencing this increase in conducting research at IH are discussed later in this report.

Thirteen studies were withdrawn from REB review by the Principal Investigator (PI) prior to receiving ethical approval. Common reasons for a PI to withdraw an application from REB review include funding application denied, decided against including any IH sites, decided to add an IH co-investigator but failed to identify one, and did not need REB approval at all as the study in question was exempt.

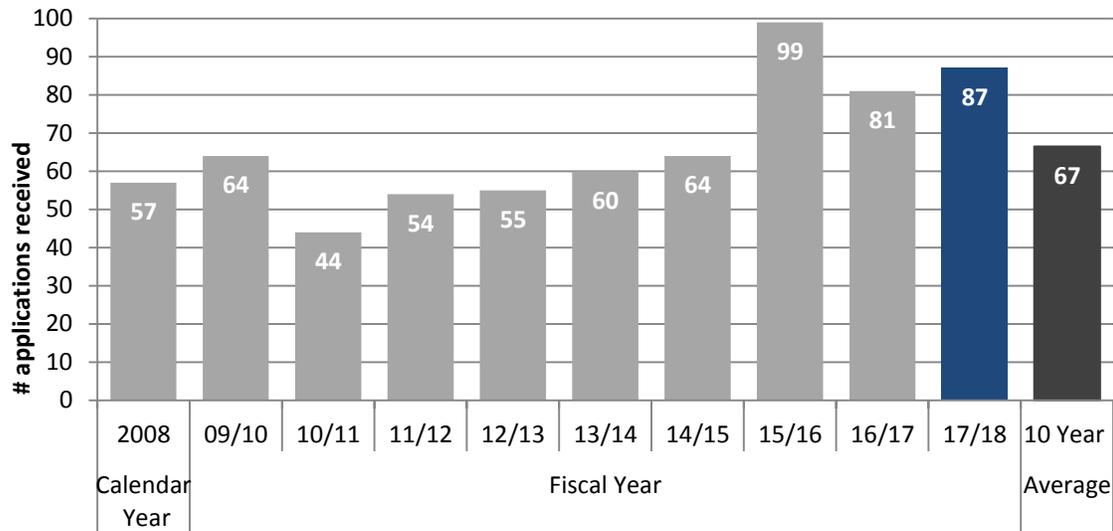


Figure 1: Number of research applications received per year by REB

10 year average = 67

2. Origin of Research Applications

The origin of an application for a new research study is defined as the primary institutional affiliation of the PI. Historically, UBC has been the largest source of new research at IH, but engagement in research by IH staff and physicians surged in 2017-18. Comparing the fiscal years for which good data are available (2011-12 to 2016-17) to the fiscal year ending March 31, 2018, we see that during the former period 29% of all research was led by IH staff or physicians. In 2017-18, this increased to 46%, representing significant growth in staff and physician engagement in research and making IH staff and physicians the largest single source of new research projects.

Credit for this growth and engagement belongs to a number of portfolios, including support for research from several vice presidents and senior leaders, facilitation provided by the IH Research Department including the establishment of a Clinical Research team in the Research Department, and several initiatives through Doctors of BC aimed at engaging physicians in research.

IH physicians and staff are actively engaged in mentoring health science students for their research projects, in addition to the clinical mentorship they provide. In total, 5 physicians, 4 pharmacists, 2 dietitians and a medical microbiologist mentored approximately 20 students undertaking 14 different research projects.

Student projects (outside of IH's participation in the training of health care professionals) are another key source of research projects conducted in IH, adding 17 student-led projects to the total. The full portfolio of student research projects includes:

- 8 Medical Resident research projects
- 7 projects from UBCO students

- 5 projects led by IH employees who were pursuing graduate degrees (3 at Royal Roads University, one at UBCO, one at Cardiff University)
- 5 projects led by graduate students not affiliated with IH (3 at UBC, 1 at Selkirk College, 1 at University of Alberta)
- 4 Pharmacy Resident research projects
- 1 Dietetic Interns research project
- 1 UBC Faculty of Medicine Summer Student Research project

As researchers across BC become aware of the advantages provided by the BC Ethics Harmonization Initiative (BCEHI)¹, they are more likely to include research sites at institutions around the province. The net result is an increase in the number of research studies conducted at IH. In 2017-18, IH participated in harmonized ethical reviews with all seven of our BCEHI partners and facilitated the ethical review of a study originating at St. Michael's Hospital (Toronto) by several partner institutions in BC.

The REB anticipates closer working relationships with academic institutions located within our region in the next couple of years. In 2017-18, we reviewed research led by faculty at College of the Rockies and Thompson Rivers University. The BCEHI Reciprocity Agreement which governs harmonized ethical review is due to be renegotiated in 2018 and it is possible that institutions local to IH, including the two aforementioned schools, may be included in the next ethics harmonization agreement. If that happens, we anticipate receiving more research applications from them.

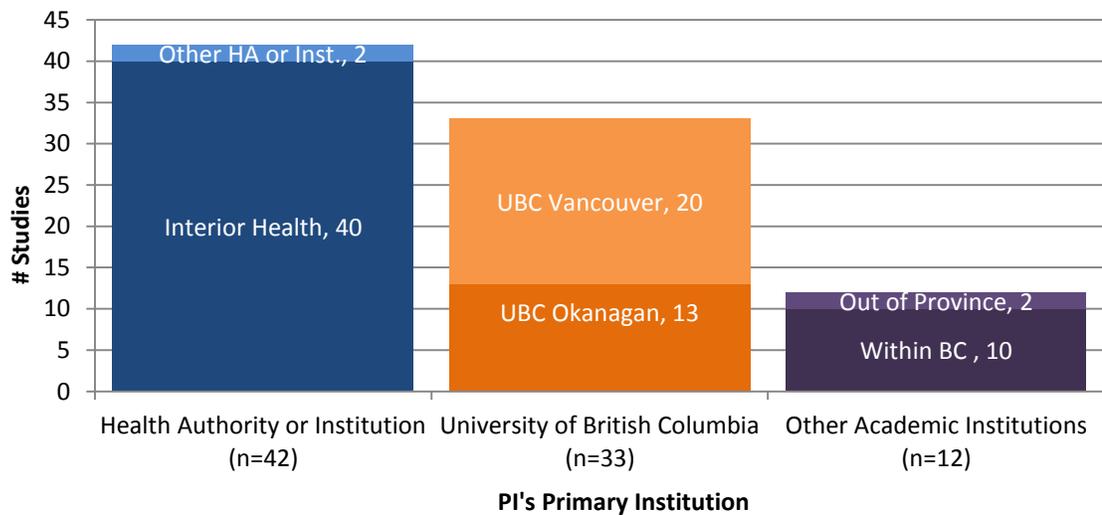


Figure 2: Origin of research by Principal Investigator's primary affiliation

¹ See Appendix 2 for a list of the eight BC Ethics Harmonization Initiative Partners

3. Categories of Research

Much of the research that is conducted in IH aligns with the institution's 5 Key Strategies: Primary & Community Care Transformation; Mental Health & Substance Use; Seniors Care; Surgical Services; and Aboriginal Health. As Key Strategies evolve from time to time, the REB categorizes research according to the broader themes articulated by the Canadian Institutes for Health Research (CIHR), the premier public funding agency for health research in Canada. The CIHR themes are: Biomedical; Clinical; Health Services; and Social, Cultural, Environmental and Population Health. A detailed explanation of each theme can be found in Appendix 3. Figure 4 shows the number of studies received in each category and illustrates the year-over-year growth in clinical research.

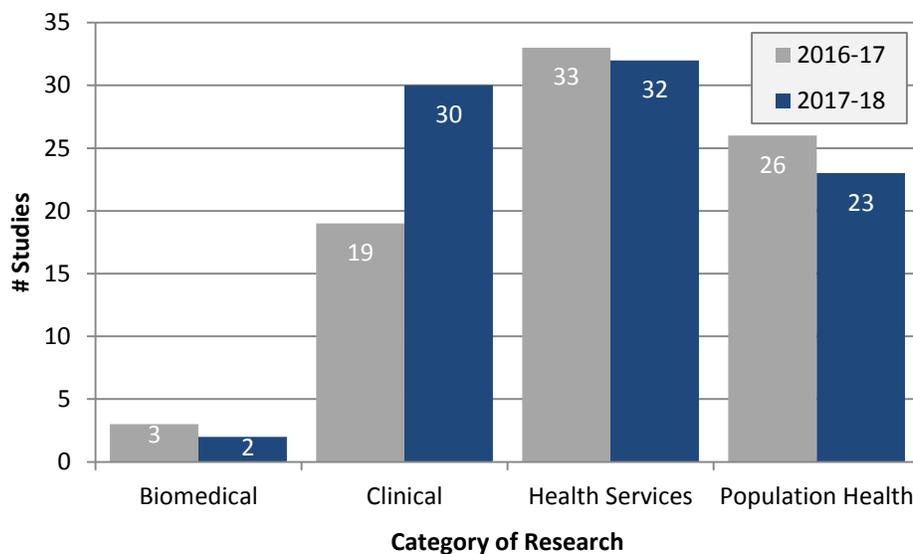


Figure 4: Number of Applications per CIHR Category of Research by year

4. Categories of Ethical Review

There are two research ethics review processes used by Canadian REBs as outlined in the TCPS2. Full board review is required for all research that is deemed to be above minimal risk, and a delegated review process is used for all research that meets the definition of minimal risk:

Research that poses no greater risk to the participants than they can reasonably expect to encounter in everyday life.

The majority of research studies reviewed by the REB are minimal-risk studies, so they are reviewed by one or two REB members on behalf of the full board. For those studies that are above minimal risk, the REB meets monthly, reviews the above minimal-risk studies, and takes a formal vote on whether or not to approve the research as

presented. When members uncover ethical concerns, these are submitted back to the researcher as provisos to be addressed; once all provisos are addressed, the ethical approval is granted.

As noted previously in this report, IH is a party to the BCEHI Agreement, which allows two or more of the eight partner institutions involved to consolidate their ethical reviews of the same study when it is carried out in different jurisdictions. Essentially, the BCEHI partners function as one REB from the perspective of the researcher, which saves the researcher considerable time and effort.

In 2017-18, the REB conducted 66% of all ethical reviews with at least one other harmonization REB partner. Figure 5 displays the breakdown of studies according to type of review, whether or not the review was harmonized, and how the numbers compare to the previous fiscal year.

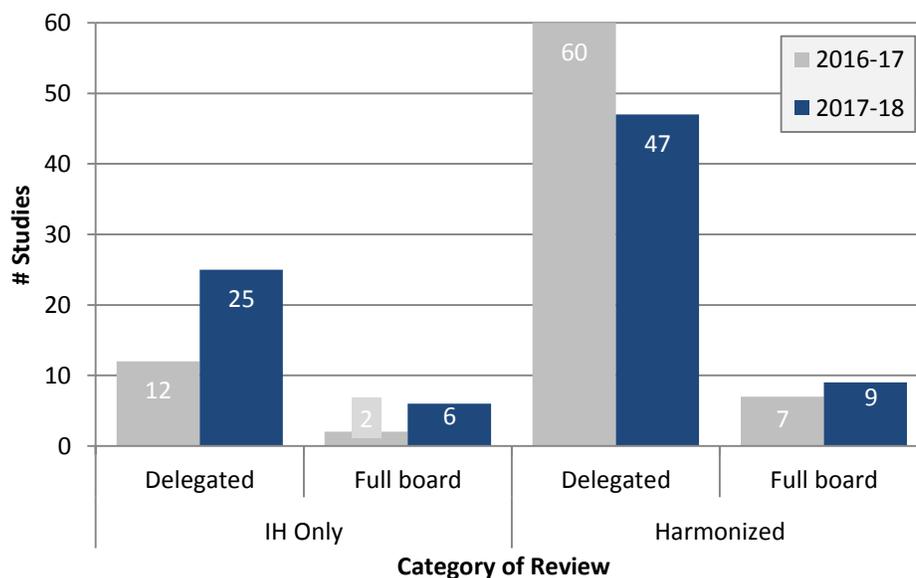


Figure 5: Number of Research Studies per Category of Review by Year

5. Continuing Review

The REB maintains oversight of all active research studies from submission to completion via review of: annual status reports submitted with applications for the renewal of ethical approval; amendments to research protocols; safety reports; and closure reports. The majority of this work is done by the Research Ethics Office staff on behalf of the REB, however if the ongoing research risk to participants is greater than minimal, the review is completed by the full board. The REB follows the guidance of Health Canada and the FDA when determining if full board review of an existing, approved study is required.

During 2017-18, the REB maintained oversight of 170 active research studies. This figure has increased from an average of 100 active research studies at any given time only 5 years ago. These studies generated 123 Renewals, 181 Amendments, 28 Safety Reports, and 67 Closures. Full board review was only required for 10 continuing review activities, but in 2018-19 the REB is considering adopting a new model of review for Safety Reports, where those reports concerning a risk to participants will receive full board review. This will replace the past practice of having a safety sub-committee of the full board meet separately to review all safety reports, including adverse event reports and protocol deviations. The new mechanism of reviewing safety reports will engage all REB members and be in line with the method of review adopted by other REBs in BC. Figure 6 displays the year-over-year increase in continuing review activities.

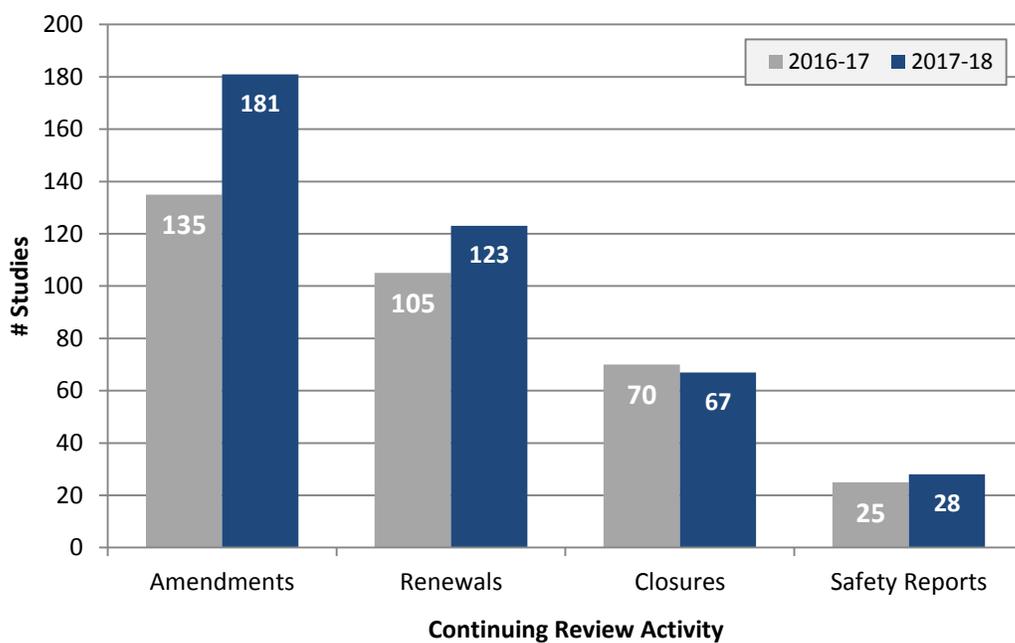


Figure 6: Number of Studies per Continuing Review Activity by Year

Of the 28 Safety Reports submitted, two were related to Serious Adverse Events (SAEs) with one local participant, and one involved a local privacy breach. In the case of the former, the SAE was expected and was managed appropriately. In the case of the latter, the Privacy Officer at the lead investigator’s site conducted an investigation and concluded that the research team managed the risk appropriately and no further action was required.

In addition, in one study in which IH was participating in a multi-site trial the REB was made aware of SAEs occurring at non-IH sites. One of these included a suspected privacy breach in Ontario. This event was investigated thoroughly and the findings revealed that no harm came to any participants.

6. Investigations

In November of 2017, the REB received a complaint from a participant in a study that had been approved jointly by the IH REB and one other REB. As per REB Policy RR1400 *Research Participant Concerns*, an investigation was launched by the Alternate Chair, Sean Gorman, PharmD. The Alternate Chair quickly responded to the complaint and over the next three months engaged the investigators of the study, IH Risk Management, the Health Care Protection Program (HCPP), and others to ensure that (a) the rights, safety and well-being of all research participants were protected and (b) the REB responded to the participant's concern in a manner that was acceptable to the participant and mitigated risks to other involved parties. A satisfactory resolution involved a change to the research protocol in January of 2018, and the Alternate Chair reported to the REB in February of 2018 that the matter was closed.

An investigation that concluded in 2015 was reopened in early 2018, due to a perceived discrepancy in how the matter was originally resolved. Specifically, there was a perceived discrepancy in what research-related activities would be permissible after the conclusion of the investigation. The area of concern pertained to whether the PI was allowed to disseminate the research findings. The Alternate Chair consulted with a key stakeholder in the original investigation, Canadian Institute for Health Information (CIHI), the Chief Medical Health Officer and VP Population Health, the former REB Chair, the Director of Risk Management, the Manager of Information Privacy & Security, the Director of Research, and the VP, Clinical Support Services & Chief Information Officer. In addition, he met with IH legal counsel who handled the matter in 2015. Based on extensive consultation, the decision was made to adhere to the final recommendations made by the REB in 2015. The matter was resolved to the satisfaction of all parties.

A third investigation involved a physician conducting clinical research without research ethics approval. This investigation was triggered by an application from this physician to the REB for a study that had clearly already been completed. The physician requested retrospective review and approval from the REB; this request was denied.

During the course of the investigation, the physician acknowledged he had published 10 research studies during his ten-plus years with IH, all without REB approval. The REO located seven of the publications and determined that all 7 met the TCPS2 definition of research involving humans therefore all seven should have had REB review.

The REB informed the physician in writing of the corrective actions required. All of them were completed promptly. The physician is aware that he must submit an application for ethical review to the REB for any future research studies that fall under IH jurisdiction. The REB also reported on the investigator and its outcome to the VP Medicine and Quality, the Director of Research, the Chief of Staff and the Site Director at the site where the physician has privileges; and the UBC Dean of Medicine, VP Research, and Director of Research Ethics.

C. Consultations

The Research Ethics Office (REO) frequently receives queries from researchers, staff and others who require ethics expertise on a wide range of research topics. Popular queries include assistance with determining if a project is research versus quality improvement or evaluation, as well as determining whether a given research project falls under the auspices of the REB.

Research Ethics staff often collaborate with other IH departments in order to determine the best course of action in response to these queries. We collaborated with Health Records, Laboratory Services, Information Privacy and Security (IPS), Medical Affairs, the Finance Department and others in order to provide the best advice and promote the high ethical standards this organization strives to achieve.

The 2017-18 fiscal year produced a record number of 68 consultations, where an average year yields 30-40 requests. This could be related to the increased profile of the REB as it enters its twelfth year of operation, and the influence of the *Ethics in Interior Health* framework in promoting an ethical culture throughout the organization.

The REB also requests consultation services on occasion, this year including the IPS Office and the Risk Management team. IPS was in relation to requests for information that contravened provincial privacy legislation (FIPPA); and Risk Management was in relation to a concern about a possible enterprise risk to IH if a particular research study was approved. Both of these concerns were resolved amicably.

D. Operations

1. Research Ethics Board Membership

The REB experienced substantial changes over the course of 2017-18, including an increase in the number of members and a change in leadership. In November of 2017, the REB Chair, Wendy Petillion stepped down as her term appointment ended, making way for a new Chair to be recruited into a position outside of the Research Department. This fulfilled one of the recommendations provided in the report *REB Current State and Recommendations* prepared at the request of the IH Scientific Director of Research in October 2016. The new Chair, Sandra Broughton, commenced her role on May 2, 2018. During the transitional period Sean Gorman, an REB member since 2014, served as Alternate Chair. The REB is grateful for the thoughtful leadership provided by Wendy for 4 years and by Sean for a relatively brief but particularly eventful period in the REB's history.

The REB also experienced turnover in physician members; at the start of the fiscal year, there were two members, but with one leaving the region and one returning to private practice, new physician members were needed. Research Ethics Office staff presented information on the REB to the Health Authority Medical Advisory Committee (HAMAC) in

September 2017 and were met with an enthusiastic response. Five new physician members were recruited and provided with the necessary training and orientation.

The REB enjoyed the active participation of two community members, one of whom needed to step down in February 2018. A search for her replacement is underway, as the Research Ethics Office works with the First Nations Health Authority and the IH Regional Aboriginal Wellness Committee to find a member with Aboriginal ancestry.

In 2017, the REB recruited three Nurse Practitioners who served for a short time as substitute members. Unfortunately, none were able to continue in their roles due to unforeseen circumstances, including the devastating wildfire season. The Clinical Lead, Nurse Practitioners expressed an interest in assisting the REB to recruit new NPs, so this will be a recruitment focus for 2018-19.

2. Research Ethics Office

The Research Ethics Board is supported by the Research Ethics Office (REO). Several changes were made in the fall of 2017 related to the REO.

- The reporting structure for the staff and functions of the REO were changed from the Director of the Research Department to the CNO & Professional Practice Lead. This change coincided with a change in reporting for the remainder of the research portfolio to the VP of Health System Planning, MHSU and Residential Services. This separation of the REO and the Research department was intentional to ensure that research ethics review was separate from research promotion.
- The term of the REB Chair came to an end and the incumbent stepped down. In her role as a Regional Practice Lead for Research, the former Chair continued to support the REO and REB with the policy review, orientation and training of new REB members, serving as an Ad Hoc member during the transition period between Chairs, and representing IH on the BC Ethics Harmonization Advisory Committee. Her many and ongoing contributions to creating an environment conducive to the ethical conduct of research are appreciated.
- The REB Coordinator position increased from a half-time role into a 0.8 FTE position in October, and to 1.0FTE effective January 2018. Primary responsibility for the day-to-day management of the REB and review of studies has been delegated to the REB Coordinator.
- Succession planning for the REB Coordinator role commenced, with the Administrative Assistant to the Chief Nursing Officer and Professional Practice Lead providing support to the REB and learning how to conduct ethical reviews. She has been a tremendous asset, enhancing the REB's web profile, streamlining meeting management, and providing expert editorial skills for numerous documents used by REB members and researchers.

As of the end of the 2017-18 fiscal year, the extensive set of 28 research ethics policies are being reviewed and revised by the REB and will ultimately go to the Senior Executive Team and the Board of Directors for approval.

3. Education

The 2017-18 fiscal year saw an intense focus on education, both because of the number of new REB members and as a result of an increase in the number of invited presentations given by the REB Chair and Coordinator. The presentation calendar included:

- Training sessions for Clinical Research Coordinators on research ethics and on writing consent forms.
- A “Research Ethics 101” presentation for the Enterostomal Therapy Nurses.
- Two presentations during IH Research Week in October 2017: one on how to obtain all of the necessary approvals to conduct research in IH, and one titled “A Beginner’s Guide to Ethics in Human Research”.
- “Patient Protections in Human Research” provided for the Patient Engagement in Research committee.
- “Navigating Projects in IH”, presented at a Physician Engagement in Research event. This presentation included information on quality improvement and evaluation projects as well as research.
- Guest lecture: “A Practical Guide to Ethics in Human Research” for Masters of Nursing students at Thompson Rivers University.
- “A Physician’s Guide to Ethics in Human Research” for the medical staff at Vernon Jubilee Hospital.
- Mentorship of student dietitians and of medical residents as they complete their mandatory research projects.

In terms of attending educational presentations, the REB Chair, Coordinator, and several members attended the first annual “REB Conference West” sponsored jointly by SFU, UBC and IH. The Chair also attended the Canadian Association of Research Ethics Boards (CAREB) conference in Halifax in May 2017.

Finally, the REB has learned from IH’s participation in the BC Ethics Harmonization Initiative. In addition to learning from and sharing best practices for research ethics with our colleagues from around the province, we have benefitted from the specialized knowledge available at our partner institutions. For example, this year the REB has partnered with BC Children’s Hospital for studies related to pediatric endocrinology and juvenile arthritis; and with Providence Health Care, SFU, and all of the other Health Authority REBs to review research on HIV/AIDS treatment.

4. Financial Report

Apart from support provided by its host institution, REBs may receive revenue through fees generated by the ethical review of research. The industry standard is that institutional REBs do not charge a fee for review of research funded by government or foundation grants, nor for research funded by unrestricted grants from the private sector.

This leaves clinical trials funded by drug or device companies as the sole source of external revenue.

When the REB was new and first created a budget, it was estimated that it would review 12 clinical trials per year, at a fee of \$1500, yielding expected revenue of \$18,000 annually. This did not materialize, but this revenue remains as a line item and is the main source of the variance in the table below.

In 2017-18, the REB reviewed 10 new clinical trials, 4 of which were industry sponsored. The remainder were sponsored by CIHR, National Institutes of Health (NIH), or other grants and were fee-exempt. Expenses were higher than normal as 5 new physician members were provided with training and orientation, in anticipation of the impact of the Clinical Research team in attracting more clinical trials to IH. Physician members are compensated as per the standards created by Physician Compensation.

REB statement of revenues & expenses for the year ending March 31, 2018

| | Actual | Budget | Variance |
|--------------------------------|----------|----------|----------|
| Revenue | | | |
| Reading fees | 0 | (18,000) | (18,000) |
| Clinical trials | (500) | 0 | 500 |
| | (500) | (18,000) | (17,500) |
| Expenses | | | |
| Wage* | 75,455 | 67,305 | (8,150) |
| Non-wage | 4,295 | 7,548 | 3,253 |
| | 79,750 | 74,853 | (4,897) |
| Total Surplus/(Deficit) | | | |
| | (79,250) | (56,853) | (22,397) |

**excludes Wage Benefits*

Source: IH Insight Financial Statements, DPT 1002.71.1102515
Prepared: June 14, 2018, J. Bradshaw

E. Summary

As research in Interior Health rapidly evolves, the REB has been responsive and adaptable. From providing educational presentations and consultation services to working with our partner REBs around the province, we have welcomed the opportunities to be leaders and change catalysts. Some highlights of the 2017-18 fiscal year include:

- Successful outreach to the IH physician community, resulting in new REB members equipped to review clinical trials;

- Recruitment of an additional pharmacist and an additional Allied Health professional as REB members;
- Contributing to the development of the Provincial Research Ethics Platform, an electronic platform which aims to streamline and simplify research ethics review around the province;
- Creation of tools and resources for internal (IH) research ethics applicants, including accessible online guidance notes for processes that generate a high volume of requests for assistance (REB Application Form and writing Consent Forms); and
- Providing a record number of invited presentations to a wide variety of audiences both within and external to IH.

1. Appendices

- REB Membership list
- CIHR four themes of research
- BCEHI list of member institutions

2. References

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2014. Retrieved from <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>.

Research Ethics Board Current State and Recommendations Report 2016

Appendix 1: REB Membership List

| Research Ethics Board Chair, 2017-18 | |
|--------------------------------------|---|
| Petillion, Wendy | To November 2, 2017 |
| Gorman, Dr. Sean (PharmD) | From November 2, 2017 to May 2, 2018 (interim position) |

| Research Ethics Board – Standing Members as at March 31, 2018 | | | | | | |
|---|-----|--------------|----------------|---|--------------------|--------------|
| Name | Sex | Member since | Highest Degree | Primary Specialty | Role | IH Affiliate |
| Armstrong, Jan | F | Aug 2016 | -- | Community member | Community Member | No |
| Arockiasamy, Dr. Vincent | M | Mar 2017 | MD | Pediatrics, Neonatal & Perinatal Medicine | Scientific | Yes |
| Golmohammadi, Dr. Kamran | M | Feb 2018 | MD | Public Health | Scientific | Yes |
| Gorman, Dr. Sean | M | Nov 2014 | PhD | Pharmacy | Scientific | Yes |
| Hale, Dr. Ilona | F | Nov 2017 | MD | Family Medicine | Scientific | Yes |
| Kjorven, Mary | F | Dec 2012 | MsN | Clinical Nurse Specialist Geriatrics | Scientific | Yes |
| Lind, Melodie | F | Aug 2017 | LL.B | Law | Legal | No |
| Mori, Dr. Julie | F | Mar 2017 | PhD | Epidemiology | Scientific | Yes |
| Nevers, William | M | Nov 2017 | PhD | Pharmacy | Scientific | Yes |
| Parker, Brent | M | Mar 2015 | MPH | Population & Public Health, Statistics | Scientific | Yes |
| Szostak, Dr. Carolyn | F | Sep 2013 | PhD | Psychology, Social Sciences, Ethics | Ethics, Scientific | No |
| Wile, Dr. Daryl | M | Nov 2017 | MD, MSc | Neurology | Scientific | Yes |

| Research Ethics Board – Substitute Members | | | | | | |
|---|--|---------------------|-----------------------|--------------------------|-------------|---------------------|
| Name | Sex | Member since | Highest Degree | Primary Specialty | Role | IH Affiliate |
| Ben Hameid, Dr. Osama | M | Nov 2017 | MD, MSc | Cardiac Surgery | Scientific | Yes |
| Bolt, Dr. Jennifer | F | Nov 2017 | PhD | Pharmacy | Scientific | Yes |
| MacAulay, Michael | M | Nov 2017 | BS | Respiratory Therapist | Scientific | Yes |
| Nicol, Judy | F | Nov 2013 | BSW | Ethics, Social Work | Ethics | Yes |
| Reiswig, Joan | F | Mar 2017 | M.ED | Dental Hygiene | Scientific | Yes |
| Slavik, Dr. Richard | M | Jun 2007 | PhD | Pharmacy | Scientific | Yes |
| Research Ethics Board - Staff | | | | | | |
| Herbert, Dorothy | Research Ethics Board Coordinator | | | | | |
| Tanahara, Atsuko | Administrative Assistant to the Chief Nursing Officer and Professional Practice Lead | | | | | |

All voting members are Canadian citizens or permanent residents of Canada.

The Research Ethics Board is organized and operates in accordance with applicable laws and regulations, including: Section 3 of the Health Canada Good Clinical Practice: Consolidated Guidelines, 1997; Part C, Division 5 of the Food and Drug Regulations, and all provincial and federal privacy legislation.

The Research Ethics Board complies with US Dept of Health and Human Services (HHS) Code of Federal Regulations Title 45, Part 46 (45 CFR 45); and the HHS Health Insurance Portability and Accountability Act (HIPAA).

Appendix 2:

The BC Ethics Harmonization Initiative (BCEHI)

BCEHI is a collaborative effort among British Columbia's regional health authorities and 4 major research universities, who collectively conduct more than 80 percent of the province's human subject ethics reviews.

Partner Organizations

Fraser Health

Interior Health

Island Health

Northern Health

Simon Fraser University

University of British Columbia* (representing multiple institutions – see below)

University of Northern British Columbia

University of Victoria

* Institutions represented by UBC

Vancouver Coastal Health

Providence Health Care

BC Cancer Agency

Children's and Women's Health Centre of BC

*Institutions affiliated with UBC for research purposes

BC Centres for Disease Control

Appendix 3: CIHR Categories of Research

The Canadian Institutes for Health Research (CIHR) is the premier public funding agency for health research in Canada. CIHR categorizes health research into 4 broad themes, and IH models its categories of research after these themes, allowing IH to articulate where it is developing expertise. The themes are:

- **Biomedical:** research with the goal of understanding normal and abnormal human functioning, at the molecular, cellular, organ system and whole body levels, including development of tools and techniques to be applied for this purpose; developing new therapies or devices that improve health or the quality of life of individuals, up to the point where they are tested on human subjects. Biomedical research may also include studies on human subjects that do not have a diagnostic or therapeutic orientation.
- **Clinical:** research with the goal of improving the diagnosis, and treatment (including rehabilitation and palliation), of disease and injury; improving the health and quality of life of individuals as they pass through normal life stages. Clinical research usually encompasses research on, or for the treatment of, patients.
- **Health Services:** research with the goal of improving the efficiency and effectiveness of health professionals and the health care system, through changes to practice and policy. Health services research is a multidisciplinary field of scientific investigation that studies how social factors, financing systems, organizational structures and processes, health technologies, and personal behaviours affect access to health care, the quality and cost of health care, and, ultimately, Canadians' health and well-being.
- **Social, Cultural, Environmental and Population Health:** research with the goal of improving the health of the Canadian population, or of defined sub-populations, through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status.