

**MEMO**

ATTENTION: Senate
c/o Rummana Khan Hemani, Registrar and Secretary to Senate

FROM: Wendy Loken Thornton, Chair, Research Ethics Board

RE: Annual REB Senate Report 2014-2015

DATE: September 14th, 2016

Dear Rummana Khan Hemani:

In accordance with Policy R20.01, "Ethics Review of Research Involving Human Participants", Section 14.7, I am submitting, on behalf of the Research Ethics Board, the Annual Report to Senate. The report spans the time frame September 1, 2014 to August 31, 2015

Sincerely,

A handwritten signature in black ink, appearing to read "Wendy Loken Thornton", with a long horizontal flourish extending to the right.

Wendy Loken Thornton, Ph.D., R. Psych.
Associate Professor, Department of Psychology
Chair, Research Ethics Board
Simon Fraser University

Enclosure

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Annual Report to Senate

September 1, 2014– August 31, 2015

Over the past year, the Simon Fraser University (SFU) Research Ethics Board (REB) and Office of Research Ethics (ORE) have continued to refine their policies and procedures to clarify the standard requirements for research submissions, kept abreast of national and provincial changes in guidelines and legislation that impact research ethics, provided ongoing education and continued to be responsive to the inquiries of our research community. In December 2014, the Panel on Research Ethics released a revised Tri-Council Policy Statement 2 (TCPS 2 (2014)). SFU ORE created a table of concordance (TCPS 2 2014 to TCPS2 2010), which was intended to facilitate a comparison between the latest edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2 2014) and the previous edition (TCPS 2 2010). This table was sent to all members of the Canadian Association for Research Ethics Boards (CAREB) to enable research administrators to easily educate their REB members and researchers on the new policy changes.

The REB membership underwent many changes over the past year. Dr. Kim Trottier, the representative to the board from the School of Business, stepped down at the end of her term in May of 2015. The board also saw the resignation of both Dr. Charlie Goldsmith, the acting Chair and a representative to the board from the Faculty of Health Sciences, and Dr. Ron Wakkary, a representative to the board from the Faculty of Communication, Art and Technology. All three individuals were thanked for their years of dedicated service to the REB. Ms. Paula Hrankowski was welcomed to the REB to fill the vacant fourth Community Member position on the board.

As part of ORE's and the SFU REB's ongoing efforts to educate students and Faculty members regarding the ethical requirements when conducting research involving human participants, the ORE has conducted seven education sessions in various SFU departments as well as hosting Brown bag monthly brown bag sessions on various topics. It is our goal, to reach out to more and more SFU departments to provide as much research ethics education and training as we can, which will lead to enhanced research ethics knowledge and ultimately improve the conduct of research involving human participants.

An abstract titled "Community-engaged research ethics" written by ORE Staff, Sarah Bennett, Holly Longstaff, and Paola Pinto Vidal, with Faculty member, George Nicholas and co-Director, POLIS Project, Kelly Bannister, was presented at the Canadian Bioethics Society Conference in May 2015. This presentation described a unique effort between ORE and the Intellectual Property Issues in Cultural Heritage (IPinCH) project to develop *collaborative research ethics guidance* for community-engaged research. The information shared in the presentation should be useful to researchers who wish to engage their ORE administrators in dialogues concerning these issues and to other similarly sized institutions that may benefit from the co-creation of research ethics guidance on topics most relevant to their participant populations.

The current membership of the REB, and current ORE staff can be found below. The Chair, Dr. Wendy Loken Thornton, and Deputy Chair, Dr. Jeremy Snyder, were both newly elected to these roles until May 31, 2016.

Current REB Membership

Elected by/from Faculty	Faculty	Term Ends
Wendy Loken Thornton (Chair)	Arts and Social Sciences	May 31, 2016
Jeremy Snyder (Deputy Chair)	Health Sciences	May 31, 2018
Peter Hall	Arts and Social Sciences	May 31, 2016
Maureen Hoskyn	Education	May 31, 2018
Paul Li	Science	May 31, 2016
Jon Axsen	Environment	May 31, 2017
Andrew Blaber	Science	May 31, 2016
Mirza Faisal Beg	Applied Sciences	May 31, 2016
Norm O'Rourke	Arts and Social Sciences	May 31, 2016

Student Members Elected by Senate		Term Ends
Iva Cheung	Graduate Student	May 31, 2017
Marion Loughheed	Graduate Student	May 31, 2017
Avleen Randhawa	Graduate Student	May 31, 2017

Elected by Senate from Community Outside SFU	Term Ends
Sarah Dadkhah	May 31, 2016
Vivian Lo	May 31, 2016
Megha Shakya	May 31, 2016
Paula Hrankowski	May 31, 2016

Office of Research Ethics

Jeffrey Toward, Director, Ex-Officio (non-voting)	Sarah Bennett, Ethics Manager
Holly Longstaff, Interim Associate Director, Ex-Officio (non-voting)	Janet Yule, Ethics Coordinator
Dina Shafey, Associate Director, Ex-Officio (non-voting)	Angela Tai, Ethics Assistant
	Paola Pinto Vidal, Office Assistant

In accordance with article 15.7 of SFU Policy R20.01 (Ethics Review of Research Involving Human Participants), the Senate approved a list of individuals, forwarded by the REB, to serve as ethicists, lawyers and medical doctors in the event that there is no elected member available with expertise in any of these areas to serve on the board. The REB has called upon these individuals on several occasions to provide their expertise in the review of research studies as required by TCPS2 (2014). Their input has become invaluable as the REB reviews more complex research studies that regularly require advice on ethical, legal and medical issues.

This year, the Canadian Association of Research Ethics Boards held their annual conference in Vancouver and all ORE staff attended. These conferences offer a great opportunity for research ethics board administrators and REB members to learn about the latest regulations and how they should be applied as well as share important tips and best practices in research ethics review with other professionals in the field.

Research Ethics Review Summary

All SFU Faculty, staff and students, who are conducting a new research study involving human participants, submit an initial application for ethical review, which must be reviewed and approved by the SFU REB and the Director/Associate Director, ORE, before any research-related procedures can begin. From September 1, 2014 to August 31, 2015, 449 (441 + 8, Figures 1 and 2) requests for initial ethical review of research were received and reviewed by the SFU REB/ORE. Additionally, there were 9 REB approved courses this past year. The continued decrease in the number of studies reviewed across 2014-2015 was reasoned to be a result of the continued application of and increased familiarity with the 2013 revisions to SFU Research Policy R20.01 which specifically exempt quality assurance, quality improvement and program evaluation studies from research ethics review. Such exemptions have permitted the SFU REB and ORE to continue to focus attention on ensuring that the rights of participants and researchers are protected in those activities deemed to be “research” as defined in both R20.01 and the TCPS2.

Figure 1: Minimal Risk Study Approvals by Academic Year

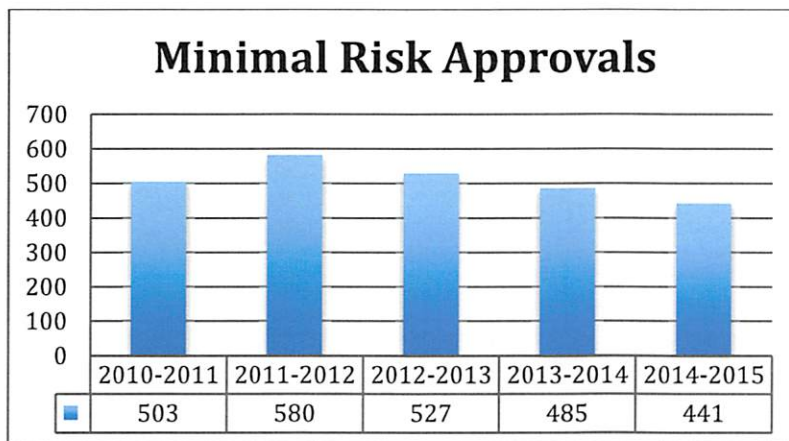
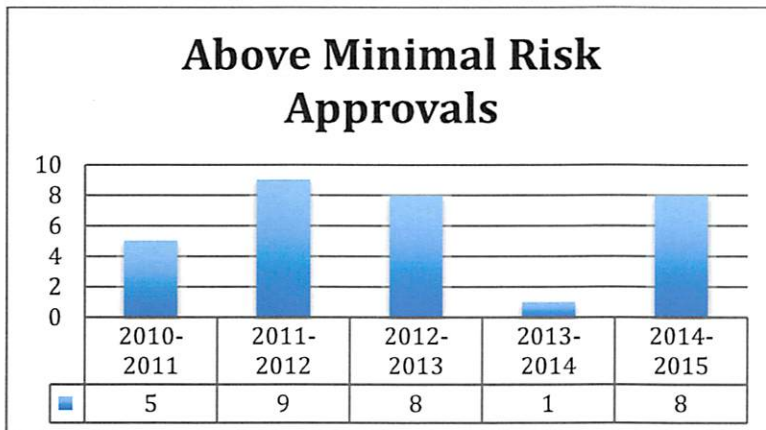
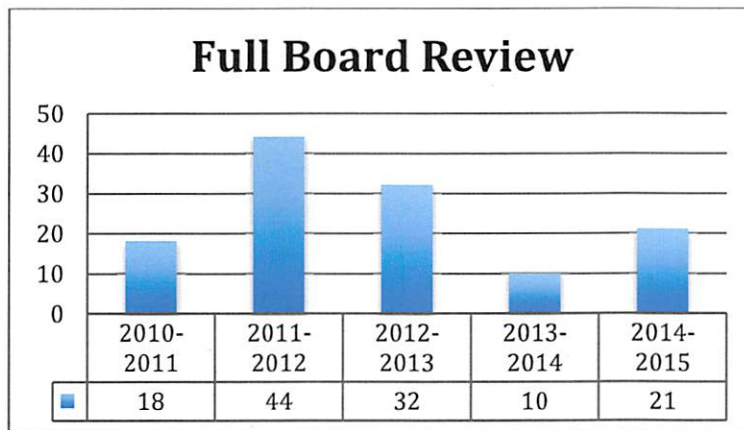


Figure 2: Above Minimal Risk Study Approvals by Academic Year



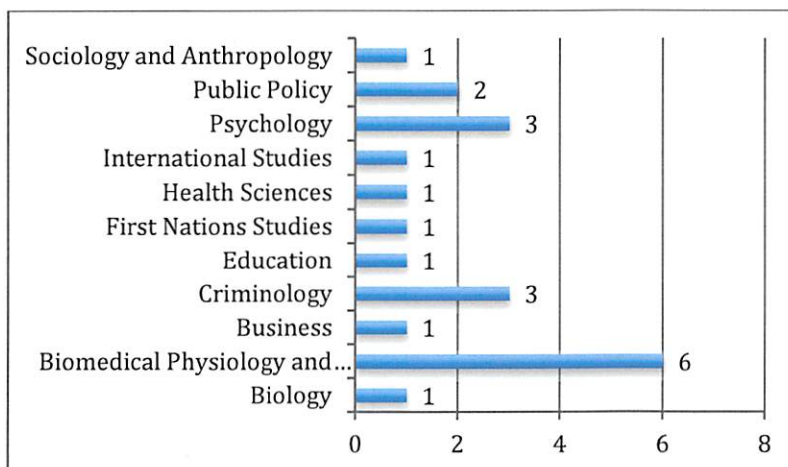
Proportionate review requires that research studies that may be designated as above minimal risk, or are more complex in nature, must be reviewed by the Full Board. Delegated review for new applications can occur when the study is considered to be of minimal risk to the prospective participants. Figure 3 highlights the number of applications that were reviewed by the Full Board.

Figure 3: Full Board Reviews Conducted by Academic Year



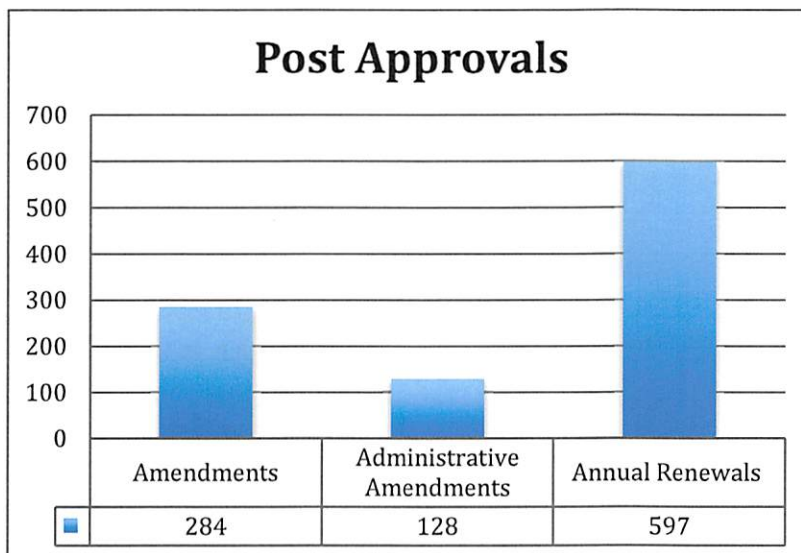
There was a marked increase in Full Board Reviews conducted in 2014-2015 compared to 2013-2014. As a result, there are still a number of complex research studies being conducted by SFU investigators that require time and effort by SFU REB members to review. As always, the goal of such reviews is to ensure participant safety and that risk to participants and researchers is properly managed and mitigated. Figure 4 shows the distribution of research studies reviewed by the Full Board for the various SFU Faculties and Departments.

Figure 4: Full Board Review Distribution of Research Studies by Discipline Type (n=21)



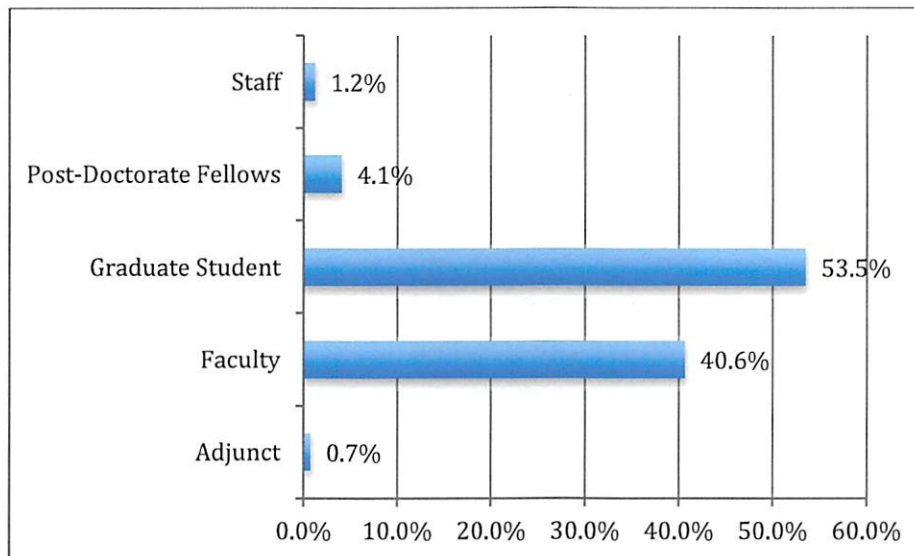
The SFU REB and ORE review and approve all post approval activities. Applications for amendments to previously approved studies are received throughout the year for studies that require changes to the research protocol, consent form(s) or other documentation. In addition any change in administrative information such as funding information or collaborator changes are acknowledged by the ORE in the form of administrative amendment approvals. The office also receives requests for annual renewals and completion of study acknowledgements as well as reports of unanticipated problems and protocol deviations as required by regulations. All amendments and annual renewals must be approved prior to execution while any unanticipated problems, protocol deviation reports, and study completion requests must be acknowledged by the office. From September 1, 2014 to August 31, 2015, 284 amendments, 128 administrative amendments and 597 annual renewals were approved by the SFU REB/ORE (Figure 5).

Figure 5: Post Approval Applications by Academic Year



Once again, graduate students serving as the Principal Investigator (PI) directed more than half of the research studies conducted at SFU during the past year (Figure 6). SFU is unique in allowing graduate students to serve as the PI for a research study. There are many challenges inherent in allowing graduate students to apply for research ethics review as the study PI because of the limited research experience accumulated to this point in their career and the unique pressures that this may place on their academic/research supervisor. However, it is believed that in permitting students to apply for research ethics review as principal investigators, SFU and the SFU REB have afforded these students an opportunity to better understand the implications of their research and how it may impact individuals, communities and themselves.

Figure 6: Distribution of Research Studies by Principal Investigator Type



Challenges Ahead

The SFU REB and ORE continue to evolve and keep current with best practices in the ethical review of research involving human participants. Policy and practice within the ORE and REB are continually being reviewed to ensure that both remain compliant with the relevant regulations and guidance that govern the conduct of research involving human participants.

Progress continues to be made with the BC Ethics Harmonization Initiative (BCEHI) with models for minimal risk and above minimal risk review having been developed. The eight partner institutions representing four of BC's major research universities and four regional health authorities implemented the minimal risk model. An evaluation of the minimal risk model took place to assess the application of the model and identify successes as well as challenges. Figures from that initial assessment show that SFU REB participated in approximately 40 harmonized study reviews. The SFU REB and staff continue to play an important role in moving this initiative forward by piloting the review models as they are developed. SFU also joined in participating in the use of the BC Common Clinical Informed Consent Form template. SFU REB staff contributed the resources necessary to create a shared harmonized approval certificate for all partner institutions to use when approving a harmonized application; this has significantly reduced administrative workload for partner REB administrative staff and researchers who had to track several approval letters for one study application.

The REB and ORE will continue to monitor any changes to institutional, provincial, national or international policy and flag any issues that may impact REB functioning or the submission and processing of applications for ethical review from the SFU researchers.