

SFU

MEMO

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

FROM: Wendy Loken Thornton, Chair, Research Ethics Board

RE: Annual REB Report to SENATE 2017-2018

DATE: October 18th, 2018

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, 2017 to August 31, 2018

Sincerely,



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

Enclosure

/jt

Annual Report to SENATE

September 1, 2017– August 31, 2018

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.

With an award from the Michael Smith Foundation for Health Research (MSFHR), the SFU ORE has continued to lead and coordinate the Research Ethics BC (REBC – formally known as BCEI) initiative throughout 2017-2018. The primary goal of this project was development of the Provincial Research Ethics Platform (PREP), which was built as part of the UBC Researcher Information System (RISe). The REBC advisory committee, with Sarah Bennett, Manager, SFU ORE as project lead and support from Paola Pinto Vidal, former SFU ORE staff, now with the Academic Health Sciences Network (AHSN) lead the development of harmonized ethics application forms and educational and communication tools for the research community. PREP launched in August 2018. REBC has truly been a success story in institutional collaboration to support making BC a more attractive research environment through harmonized, expert human participant research ethics review.

In June of 2018, the SFU ORE, in partnership with UBC and UBC-O jointly organized a conference designed to provide an educational and networking event for researchers, REB members and research ethics administrators from institutions across western Canada. The 2nd annual conference (REB West 2018) was organized with a specific emphasis on reaching those individuals working in research ethics at newer and smaller universities and colleges.

The conference, once again, was extremely well received with over 80 participants from 30 different institutions from across BC and Alberta. The conference featured a series of plenary sessions across two days that explored both fundamental and emerging issues faced by REBs today. Presentations reflected the varied experiences of our panel members while being firmly grounded in research ethics policy. The conference provided a premier interdisciplinary platform for participants to present and discuss the most recent innovations, trends and concerns as well as practical challenges encountered and solutions adopted in the field of Research Ethics Review.

Starting in December 2018, Simon Fraser University will commence a gradual implementation of a series of interlinked software products, collectively termed "SFU's Research Administration System," hosted at the SFU Data Centre. The Human Ethics module will be the first to launch in the SFU Research Administration System. SFU ORE staff, under the leadership of Dr. Dina Shafey, Associate Director, have worked extensively in 2018 to create the forms, test the development of the new system, and prepare for migration from the current system to the new system. The new Human Ethics module will permit researchers to track their applications through the review process, to designate others to complete an application for the principal investigator, to have their approvals submitted directly to Research Services for access to their funds and will link with other modules allowing all communications and required actions to be managed in one system. In addition, the newly created dynamic forms within the Human Ethics module will aid researchers by providing the appropriate and required information needed to assist in the review of their human ethics applications.

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 reelected to these roles until May 31, 2019. We thank the following individuals for their service as REB members this past year: Dr. Peter Hall, Faculty Member, Dr. Andrew Blaber, Faculty Member, Dr. Maureen Hoskyn, Faculty Member, Michael Chua, Graduate Student Member, and Christine Wang, undergraduate student member.

Current REB Membership

Elected by/from Faculty	Faculty	Term Ends
Wendy Loken Thornton (Chair)	Arts and Social Sciences	May 31, 2019
Jeremy Snyder (Deputy Chair)	Health Sciences	May 31, 2021
David MacAlister	Arts and Social Sciences	May 31, 2019
Engida Gebre	Education	May 31, 2021
Sonia Luehrmann	Arts and Social Sciences	May 31, 2019
David Whitehurst	Health Sciences	May 31, 2019
Victoria Claydon	Science	May 31, 2019
vacant	Science	May 31, 2019
Geoffrey Poitras	Business	May 31, 2021
Carman Neustaedter	Communication Arts and Technology	May 31, 2019
Teresa Cheung	Applied Science	May 31, 2019
Valorie Crooks	Arts and Social Sciences	May 31, 2020

Student Members Elected by Senate	Role, Faculty or Department	Term Ends
Iva Cheung	Graduate Student, Health Sciences	May 31, 2019
Evan Hutcheon	Graduate Student, Biomedical Physiology and Kinesiology	May 31, 2019
Vienna Lam	Graduate Student, Criminology	May 31, 2019
Camelia Tavakoli	Undergraduate Student	May 31, 2019

Elected by Senate from Community External SFU	Term Ends
Paul Hrankowski	May 31, 2019
Anita Haidar	May 31, 2019
Mikelle Sasakamoose	May 31, 2019

Office of Research Ethics

Jeffrey Toward, Director, Ex-Officio (non-voting)	Hanna Jones-Eriksson, Officer
Dina Shafey, Associate Director, Ex-Officio (non-voting)	Alanna Dyck, Officer
Sarah Bennett, Manager	Candase Jensen, Ethics 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 the required expertise to serve on the board. The REB has called upon the lawyers and medical doctors on several occasions to provide their expertise in the review of research studies as required by TCPS 2 (2014). Their input has become invaluable as the REB reviews more complex research studies that regularly require advice on legal and medical issues. The ORE would like to thank Dr. Tamara O’Doherty, Dr. Malcolm Steinberg, and Dr. Charlotte Waddell for their continued and valued contributions to the board as our experts knowledgeable in law and medicine.

The ORE would also like to acknowledge the contributions made by Dr. Ruth Laverne, Dr. Stephen Robinovitch and Dr. Atiya Mahmoud, all of whom have stepped up to fill immediate short-term vacancies on the REB as other members have had to step away, both temporarily and permanently, from their role on the board. The REB would not have been able to function without the significant contributions made by these individuals.

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 Associate Director, ORE, before any research-related procedures can begin. From September 1, 2017 to August 31, 2018, 547 requests for initial ethical review of research were received and reviewed by the SFU REB/ORE. The number of requests for initial ethical review have steadily increased over the past three years (Figure I). Not included in this total for 2017-2018 are the 92 new harmonized¹ research ethics reviews the SFU REB/ORE has also participated in.

Figure 1: New Research Ethics Application Submissions by Academic Year



^{1 1} Harmonized in this context is defined as research ethics review conducted jointly with one or more institutions (e.g. Health Authority REB or University REB).

The SFU REB and the ORE understand the need to review research ethics applications efficiently so as not to delay researchers in conducting their research studies. The ORE has begun to monitor queue time, the length of time it takes from submission to when the principal investigator received their first review (Figure 2) and the length of time from submission to approval (Figure 3). The average queue time over the 2017-2018 year was 13.6 business days and the average submission to approval time was 24.5 business days.

Figure 2: Average Queue Time (Business Days) per Month during the 2017-2018 Academic Year

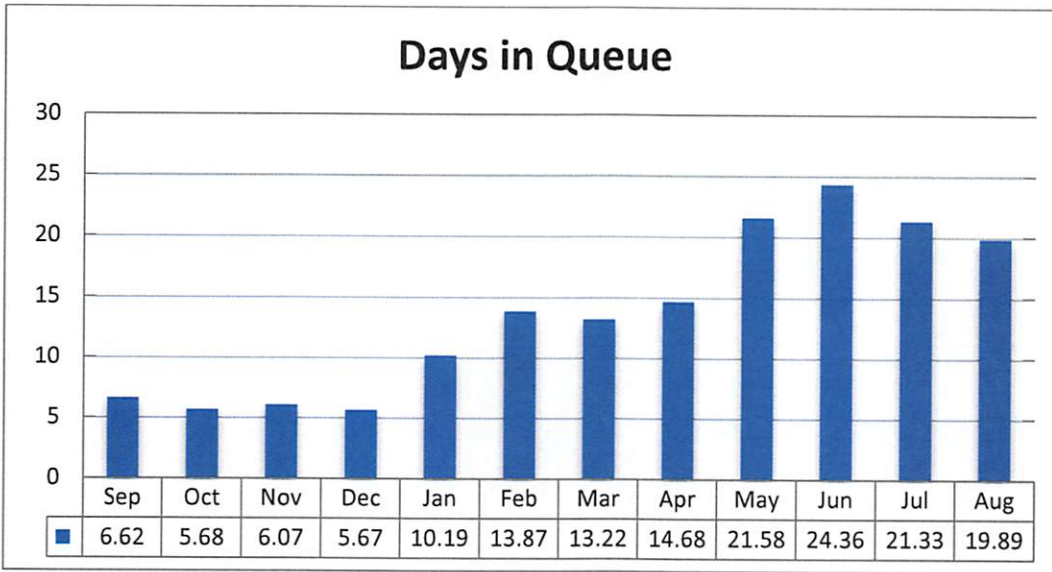
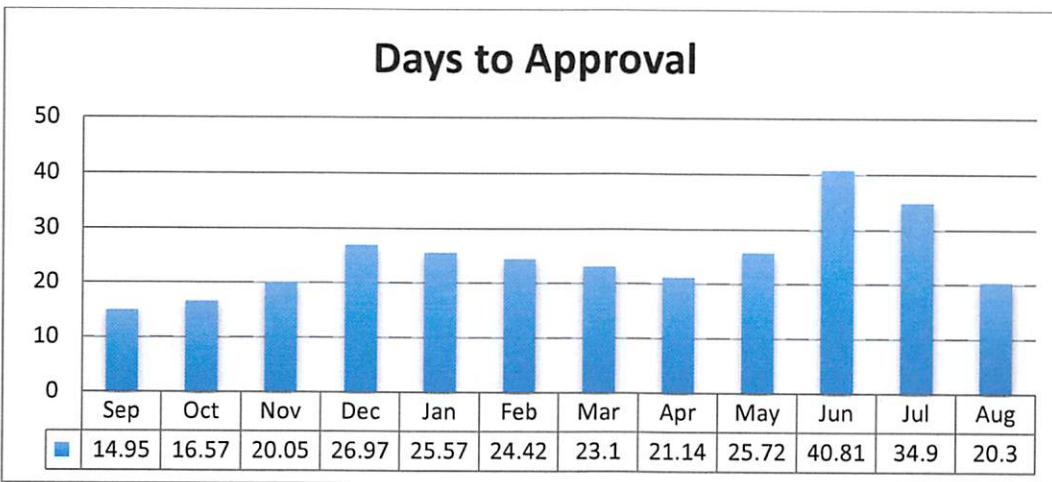


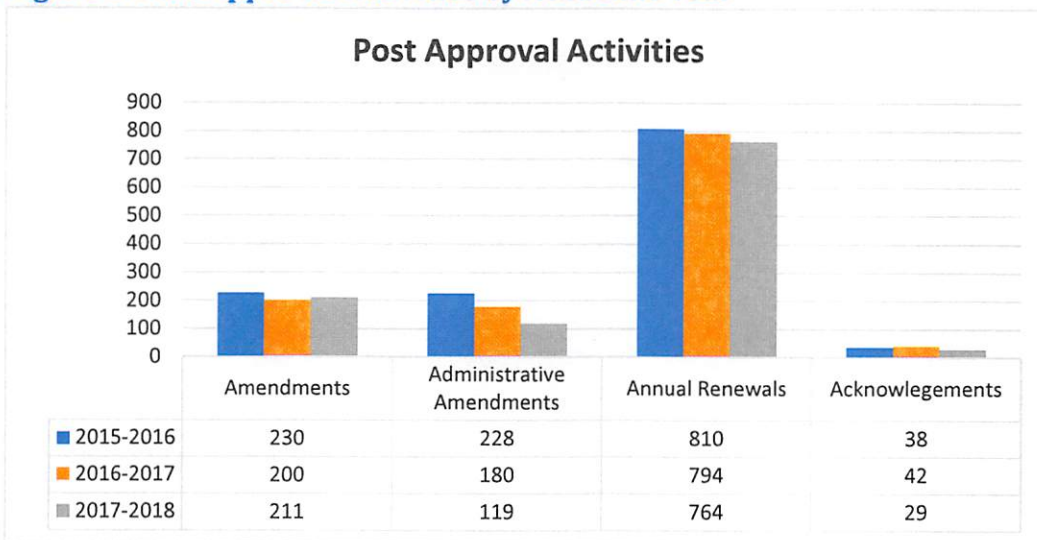
Figure 3: Average Days (Business Days) to Approval per Month during the 2017-2018 Academic Year



Research ethics review does not end once a study has received initial approval. The SFU REB and

ORE review and approve all post approval activities (Figure 4). 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 executing any changes to the approved research while any unanticipated problems, and protocol deviation reports must be acknowledged by the office. Not included in these post approval totals for 2017-2018 are the 194 harmonized² post approval ethics reviews the SFU REB/ORE has also participated in.

Figure 4: Post Approval Activities by Academic Year



Every study that is approved is designated as either Minimal Risk (Figure 5) or Above Minimal Risk (Figure 6). Note the number of approvals in Figure 5 and Figure 6 do not sum to the total number of new research ethics application submissions since not all studies have yet been approved. Additionally, there were 14 REB approved courses this past year.

² Harmonized in this context is defined as research ethics review conducted jointly with one or more institutions (e.g. Health Authority REB or University REB).

Figure 5: Minimal Risk Study Approvals by Academic Year

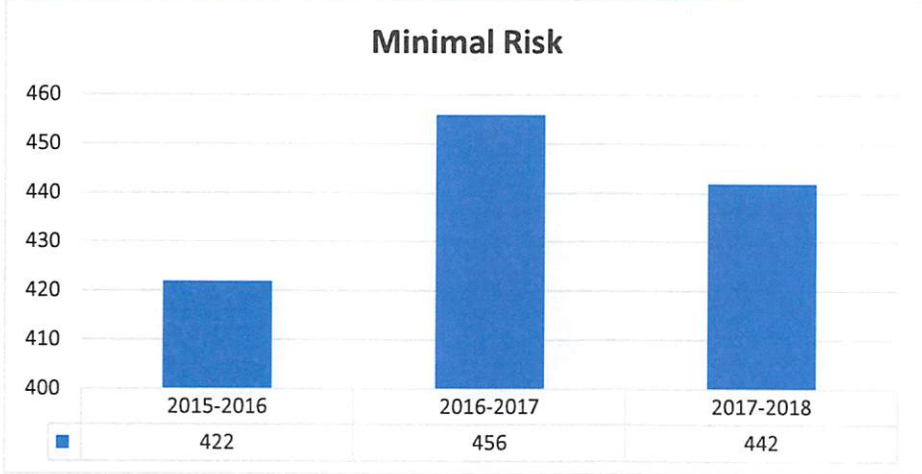
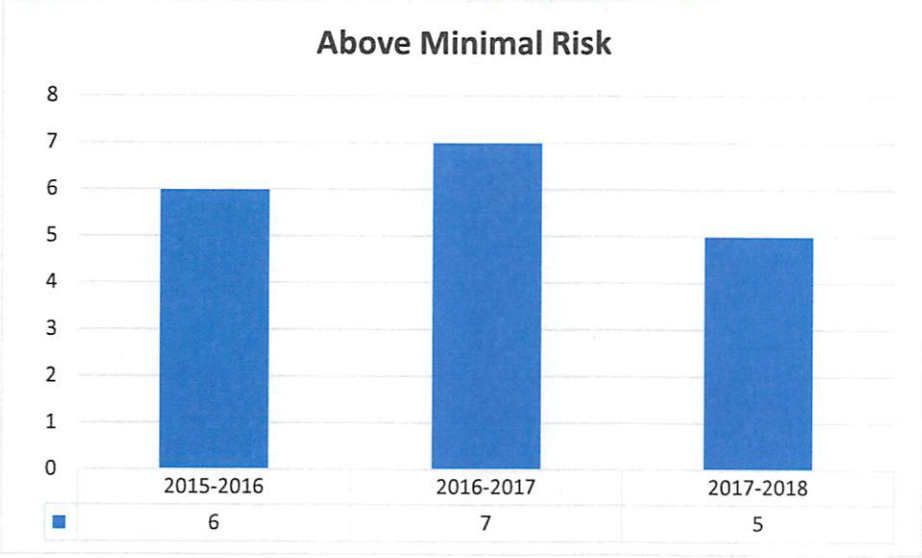
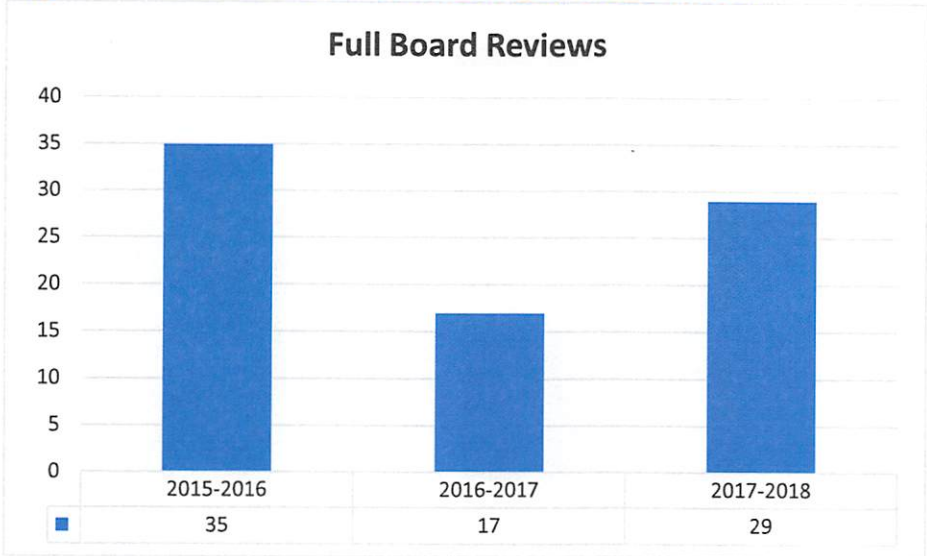


Figure 6: Above Minimal Risk Study Approvals by Academic Year



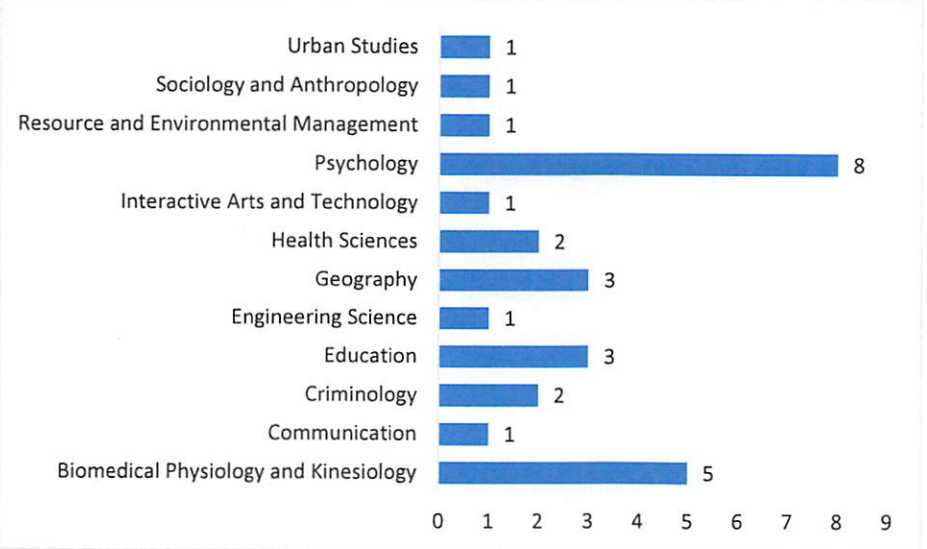
Proportionate review requires that research studies that may be designated as above minimal risk or are more complex in nature must be reviewed by the Full Board. Delegated review for new applications can occur when the study is considered to be of minimal risk to the prospective participants. Figure 7 highlights the number of applications that were reviewed by the Full Board.

Figure 7: Full Board Reviews Conducted by Academic Year



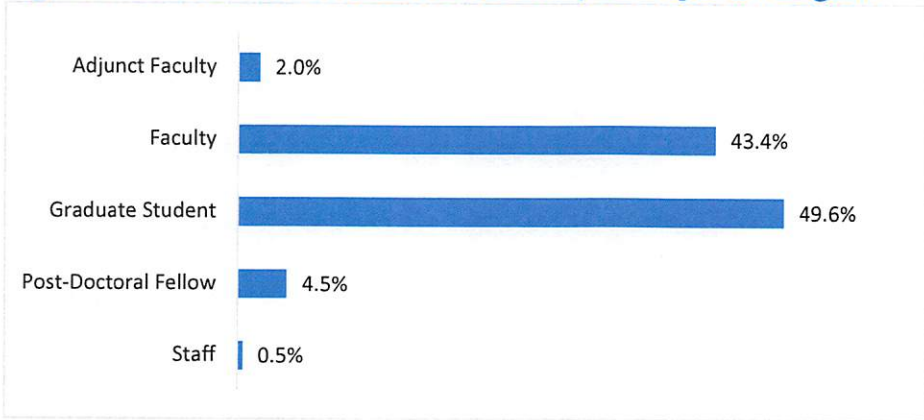
The goal of Full Board reviews is to ensure participant safety and that risk to participants and researchers is properly managed and mitigated. The number of reviews conducted at the Full Board increased in 2017-2018, as did the complexity of the studies submitted. In the future, the Faculty REB members will become more involved in the delegated reviews of research ethics applications as the ORE moves away from having the Associate Director, ORE, review and approval all minimal risk research studies. This may result in a decrease in the number of studies going to the Full Board moving forward. Figure 8 shows the distribution of research studies by discipline reviewed by the Full Board.

Figure 8: Full Board Review Distribution of Research Studies by Discipline (n=29)



Once again, graduate students serving as the Principal Investigator (PI) directed half of the research studies conducted at SFU during the past year (Figure 9). 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 set of challenges 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 9: Distribution of Research Studies by Principal Investigator



ORE Outreach

Major changes have taken place over the last few years with regard to the procedures and principles one must adhere to at the institutional, national and international level. The REB members and ORE staff believe in the necessity of educating SFU researchers (Faculty, staff and students) regarding the policies and legislation that all research conducted with human participants must follow in order to change the culture in relation to the ethics approval process. To this end, in the past year the ORE has given over 30 guest lectures in undergraduate and graduate level classes and workshops and provided over 100 face to face meetings with SFU researchers.

The REB and the ORE understand the importance of professional development to ensure we are educating the SFU research ethics community appropriately regarding new policies and procedures and understanding how research ethics review applies to new and diverse research approaches. The REB and ORE have attended and presented at a number of workshops and educational events.

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.

As we move towards the implementation of a new Human Ethics online application system there will be challenges as we migrate to the new system. ORE will not be accepting new applications, amendments or renewals from November 23, 2018 to January 2, 2019. This shutdown will enable ORE to review all studies submitted in the old system before they are migrated to the new system. In addition, this time will allow ORE to pilot a few new ethics applications into the new system to test for any bugs in the system before the University wide launch on January 2, 2019. ORE has communicated this information to researchers in different ways across campus and are continuing to communicate this information out. There will be opportunities to train faculty and students on this new system and the communication about training will be sent out closer to the launch of the Research Administration System.

In the near future, SFU must create an institutional policy in response to TCPS 2, Article 5.1, that explains the nature and extent of an institutions' responsibilities to "support their researchers in maintaining promises of confidentiality" where complying with legal obligations would conflict with those promises. The Tri-Agencies have directed institutions to a public interpretation from the Panel on Research Ethics. This interpretation specifically states that where there is a conflict between researchers' ethical and legal obligations, institutions must provide financial and other support for researchers to obtain independent legal advice or ensure that such support is provided. Going forward, the Agencies have indicated that they will apply this interpretation when questions arise regarding an institution's obligation of support for researchers facing possible challenges to their promises of confidentiality. Consequently, since SFU is involved with research that may present its researchers with a conflict between their ethical and legal obligations, SFU must establish a policy that explains how it will fulfill that obligation. This policy must include an explanation of the nature and scope of the support, a mechanism to determine the level of support in individual cases, the source of funding and any other relevant criteria.

The SFU REB and ORE also need to revise R20.01 so that it remains current and compliant with the TCPS 2 (2014) and other provincial, federal and international guidelines and policies that govern the conduct of research involving human participants. As part of any potential revision, the REB has strongly indicated the need for more flexibility and responsiveness in board appointments to help address the increasingly complex studies submitted for ethics review.

In recognition of the Truth and Reconciliation Council and SFU Aboriginal Reconciliation Council report, the REB and the ORE are reevaluating how research ethics review is conducted at SFU when the research involves Indigenous peoples and communities. The REB and ORE will be moving forward in a consultative process with SFU Indigenous Faculty researchers, student researchers and the Indigenous community to develop guidelines and best practices for research conducted with Indigenous communities. In addition, this consultative process may lead to other initiatives to improve and increase the research that is conducted with these communities. The REB and ORE are also exploring ways to increase indigenous representation on the REB.

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.