



MEMO

ATTENTION: Senate
c/o Mark Walker, Registrar and Secretary to Senate

FROM: Charles Goldsmith, Chair, Research Ethics Board

RE: Annual REB Senate Report 2013-2014

DATE: October 15th, 2014

Dear Mark Walker:

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, 2013 to August 31, 2014.

Sincerely,

A handwritten signature in black ink, which appears to read "Charlie H Goldsmith". The signature is fluid and cursive, written over a light blue horizontal line.

Charles H. Goldsmith, Ph.D.
Professor, Faculty of Health Sciences
Chair, Research Ethics Board

Enclosure

/jt

Annual Report to Senate

September 1, 2013– August 31, 2014

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.

Revised guidance documents and forms have been created for the *Acknowledgement* of REB receipt of information specific to an application, *Amendment* requests, *Annual Renewals*, *Unanticipated Problem* reporting, *Change of Principal Investigator* reporting, and *Completion of Study*. An *Application for Externally Approved Research* form was created to handle requests from external investigators who have already received REB approval from their home institution but wish to use SFU resources in the conduct of their research. A *Protocol Review Checklist* was created to assist REB functioning and to ensure that the review of studies funded by United States (US) federal agencies is compliant with the relevant federal regulations/guidelines. An *Ethics Requirements Checklist for Graduate Students* was also created to help students better understand the ethics review process and to help them determine if their study needs review.

The REB also approved the transition away from the use of the ORE Graduate student tutorial to the *Course on Research Ethics (CORE)* tutorial developed by the Interagency Advisory Panel on Research Ethics. The decision to move to the CORE tutorial was based on the fact this it is updated as the Tri-Council Policy Statement (TCPS2) is updated making it a relevant and consistent training tool in research ethics for all researchers and the logical successor to the previously used ORE Graduate Student tutorial. The change from the ORE Graduate student tutorial to the CORE tutorial will take place on September 1st, 2014. It is important to note that the CORE Tutorial is used Canada-wide as well as internationally in over 67 countries.

The SFU REB and ORE have undergone a number of changes in the past year. Within the ORE, Dr. Jeffrey Toward was hired as the new Director in November 2013, filling a vacancy left when Dr. Hal Weinberg retired earlier in the year. Ms. Sarah Bennett also joined the ORE in November as the Ethics Manager, replacing Ms. Barb Zollinger who retired in December after many years of exceptional service to the office. Dr. Dina Shafey, Associate Director ORE, began a maternity leave in November and was replaced on an interim basis by Drs. Kirsten Bell and Holly Longstaff.

The REB membership underwent many changes over the past year. Dr. Nadine Schuurman, the representative to the board from the Faculty of Environment, stepped down at the end of her term in May of 2014. The board also saw the resignation of Ms. Margit Nance, a representative to the board from the community. Both Dr. Schuurman and Ms. Nance were thanked for their years of dedicated service to the REB. Dr. John Axsen was then welcomed to the REB as the new representative from the Faculty of Environment. Ms. Avleen Randhawa joined the REB as the third graduate student representative to the board. A new representative has not yet been found to fill the vacant fourth Community Member position on the board. This vacancy may provide the opportune time to have a representative from the First Nations/Aboriginal community join the board since SFU conducts a great deal of research with this community. 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 in the event that there is no elected member available with expertise in ethics to serve on the board. The REB now has three lists of qualified individuals (Ethicists, Lawyers and Medical Doctors) to call upon to ensure that the board is properly constituted according to TCPS2 REB membership requirements..

The current membership of the REB, and current ORE staff can be found below. The Chair, Dr. Charles Goldsmith, and Deputy Chair, Dr. Andrew Blaber, were both re-elected to these roles until May 31, 2015.

Current Members

| Elected by/from Faculty | Faculty | Term Ends |
|--------------------------------|-----------------------------------|------------------|
| Charles Goldsmith (Chair) | Health Sciences | May 31, 2016 |
| Andrew Blaber (Deputy Chair) | Science | May 31, 2016 |
| Ron Wakkary | Communication, Art and Technology | May 31, 2016 |
| Mirza Faisal Beg | Applied Sciences | May 31, 2016 |
| Wendy Thornton | Arts and Social Sciences | May 31, 2016 |
| Peter Hall | Arts and Social Sciences | May 31, 2016 |
| Norm O'Rourke | Arts and Social Sciences | May 31, 2016 |
| Kim Trottier | Business Administration | May 31, 2015 |
| Maureen Hoskyn | Education | May 31, 2015 |
| Jeremy Snyder | Health Sciences | May 31, 2015 |
| Paul Li | Science | May 31, 2016 |
| John Axsen | Environment | May 31, 2017 |

Student Members Elected by Senate

| | | Term Ends |
|-----------------|-----------------------|------------------|
| Ehsan Jozaghi | Graduate Student | May 31, 2015 |
| Marc Legacy | Graduate Student | May 31, 2015 |
| Avleen Randhawa | Graduate Student | May 31, 2015 |
| Grant Crossley | Undergraduate Student | May 31, 2015 |

Elected by Senate from Community Outside SFU

| | Term Ends |
|---------------|------------------|
| Sarah Dadkhah | May 31, 2016 |
| Vivian Lo | May 31, 2016 |
| Megha Shakya | May 31, 2016 |

Office of Research Ethics

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| Jeffrey Toward, Director, Ex-officio (non-voting) | Sarah Bennett, Ethics Manager |
| Kirsten Bell, Interim Associate Director, Ex-officio (non-voting) | Janet Yule, Ethics Coordinator |
| Holly Longstaff, Interim Associate Director, Ex-officio (non-voting) | Angela Tai, Ethics Assistant |
| Dina Shafey, Associate Director, Ex-officio (non-voting) | Paola Pinto Vidal, Office Assistant (1/2 time) |

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. 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. The office also receives requests for annual renewals and completion of study acknowledgements as well as reports of unanticipated problems and protocol deviations. 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, 2013 to August 31, 2014, 486 (485+1, see figures 1 and 2) requests for initial ethical review of research were received and reviewed by the SFU REB/ORE. Additionally, there were 12 REB approved courses this past year. The continued decrease in the number of studies reviewed across 2013-2014 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 REB and ORE to continue to focus attention on ensuring that the rights of participants, researchers and SFU are protected in those activities deemed to be “research” as defined in both R20.01 and the TCPS2. All studies that were reviewed eventually received approval.

Figure 1: Minimal Risk Study Approvals by Academic Year

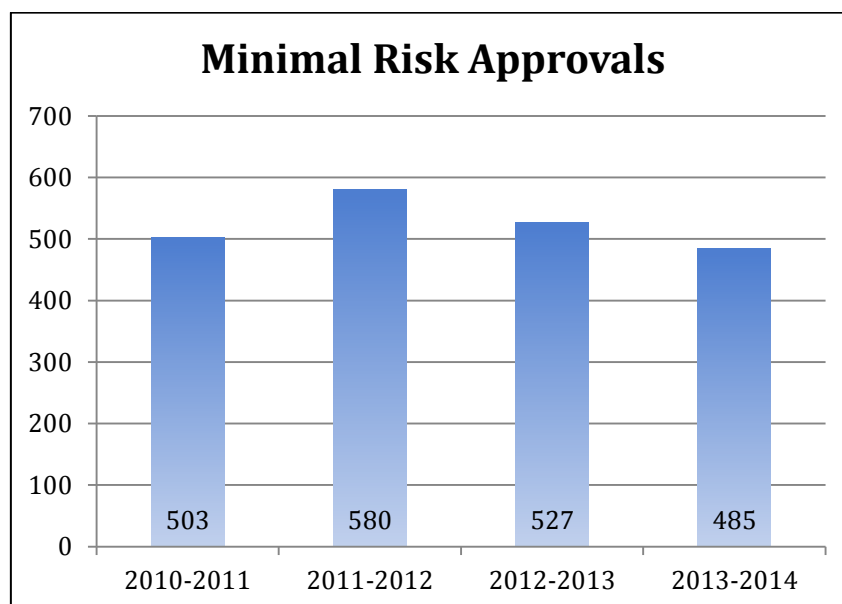
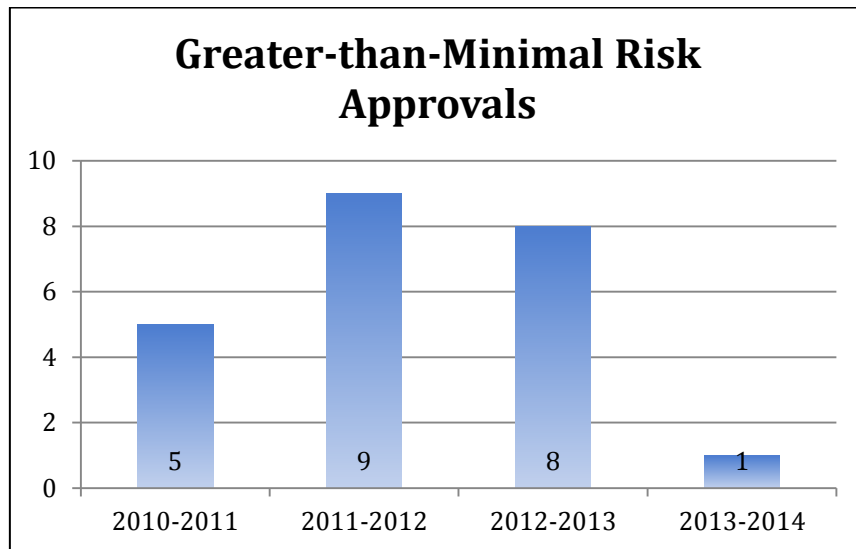
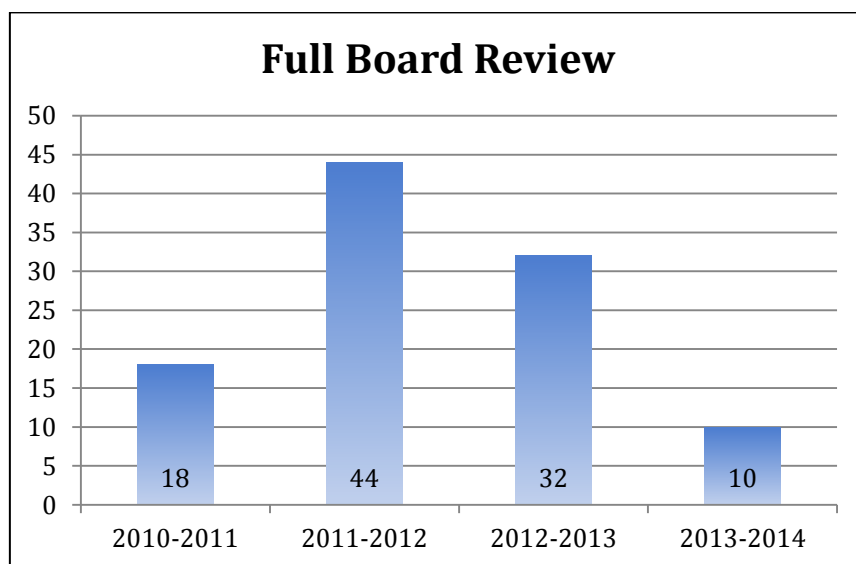


Figure 2: Greater-Than-Minimal Risk Study Approvals by Academic Year



Proportionate review requires that research studies that may be designated as greater-than-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.

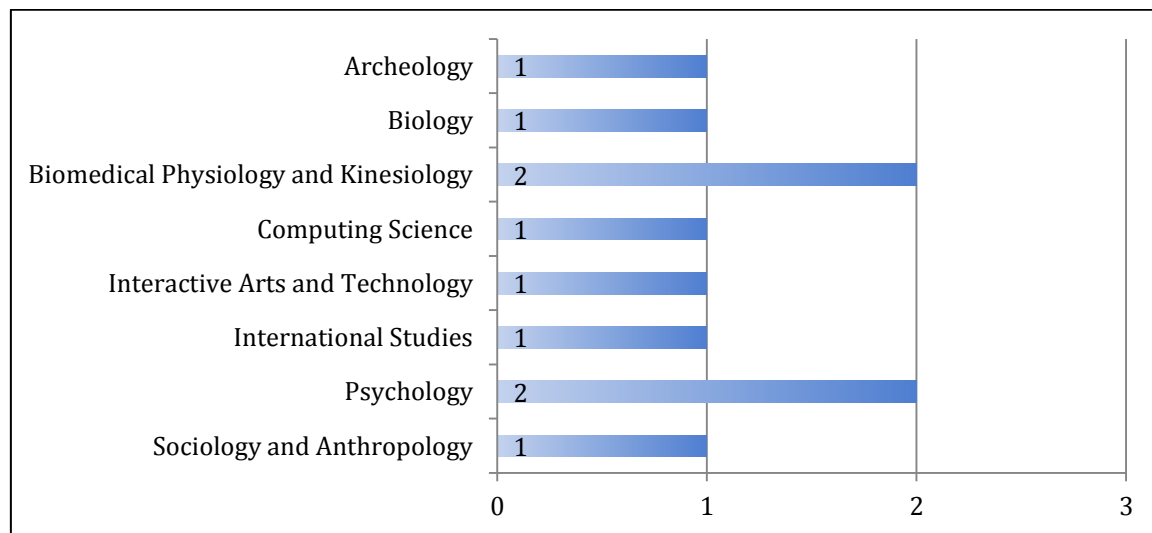
Figure 3: Full Board Reviews Conducted by Academic Year



There was a marked decrease in Full Board Reviews conducted in 2013-2014 compared to both 2012-2013 and 2011-2012. As was noted in the 2012-2013 report, this decrease is likely attributed to the BC Research Ethics Review Reciprocity Agreement signed by the eight participating BC universities and Health Authorities that was executed in May of 2013. This reciprocity agreement permits the SFU REB/ORE to conduct delegated reviews of Full Board research studies when there is an SFU co-investigator and the research study has received Full Board review from one of the other institutional signatories to the agreement. Those studies that have SFU Principal Investigators or are based primarily out of SFU are forwarded to one of the SFU REB subcommittees for Full Board review. As a result, there are still a number of complex research studies being conducted by SFU investigators that require time and effort by 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.

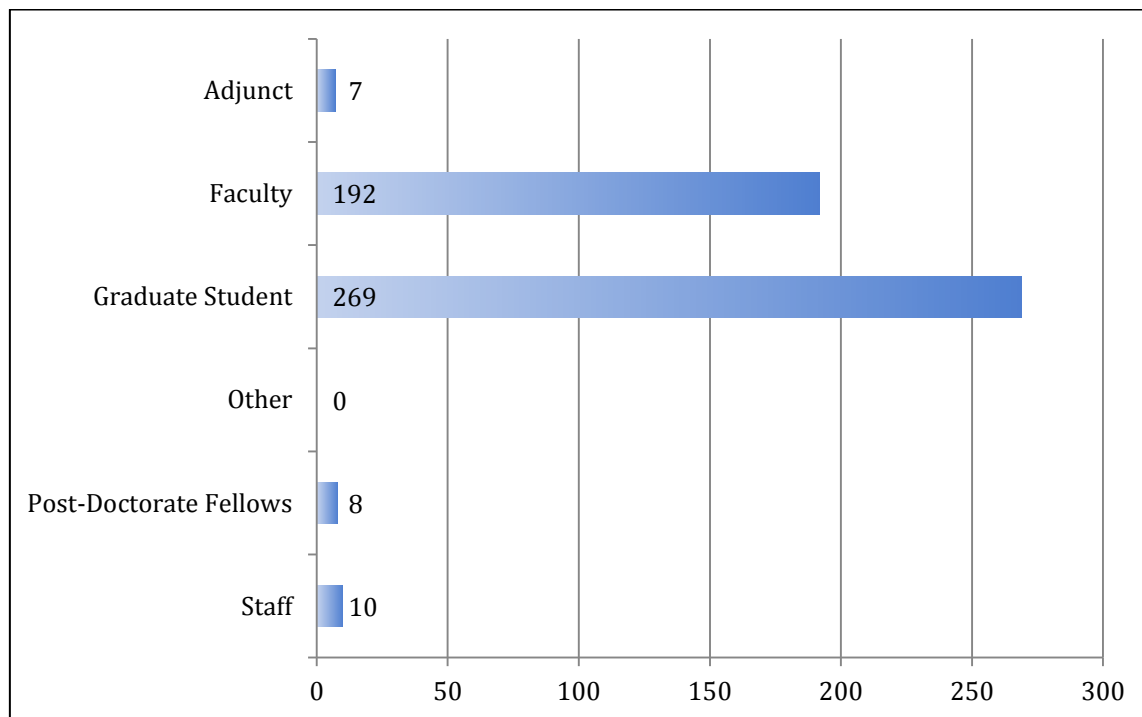
Figure 4 shows the distribution of research studies reviewed by the Full Board for various SFU Faculties and Departments.

Figure 4: Full Board Review Distribution of Research Studies by Discipline Type (n=10)



Once again, more than half of the research studies conducted at SFU during the past year were directed by graduate students serving as the Principal Investigator (PI) (Figure 5). 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 5: Distribution of Research Studies by Principal Investigator Type (n=486)



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. The recent transition to the CORE tutorial will assist in this effort as any revisions to the TCPS2 guidelines should quickly be reflected in the tutorial as both are maintained by the Interagency Advisory Panel on Research Ethics.

The recent move to three REB subcommittees (Biomedical and Health Research, Clinical Trials, Behavioural and Social Sciences Research) will continue to be monitored to ensure that membership resources are appropriately being utilized across this relatively new three sub-committee meeting format.

Progress continues to be made with the BC Ethics Harmonization Initiative (BCEHI) as a model for minimal risk review has been developed and will be piloted by the eight partner organizations representing four of BC's major research universities and four regional health authorities. The ultimate goal of the BCEHI is to develop harmonized models of ethics review that will allow researchers to submit a single application for review, regardless of the number of partners

involved in a study. The SFU REB will continue to play an important role in moving this initiative forward by piloting the review models as they are developed.

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 research community.