St. Thomas University Research Ethics Board Annual Report 2015-2016

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and

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Research Ethics Board Annual Report 2015-2016

Consistent with the responsibility requirements established in the Research Ethics Board Policy (approved by Senate, 2016), this report summarizes the responsibilities and activities of the REB from July 01, 2015 to June 30, 2016.

Responsibilities of the Research Ethics Board

(Article 1.2, St. Thomas University Research Ethics Board Policy)

St. Thomas University Research Ethics Board (REB) is responsible to the President or their designated representative through the Associate Vice-President (Research) of St. Thomas University for:

- developing policies regarding ethical issues relating to the use of human participants in research;
- reviewing all protocols requiring the participation of human participants for ethical approval;
- reviewing annually all policies regarding ethical issues relating to the use of human participants in research projects to ensure that policies remain current;
- dealing with matters concerned with human-based research referred to the REB by the President or their designate of STU;
- monitoring ongoing research and terminating any project that does not conform to ethical standards;
- responding to inquiries from external agencies with responsibility to monitor ethics review procedures at the University;
- preparing an annual report for submission to the President or their designate;
- participating in continuing education in matters relating to ethics and the use of human participants;

organizing educational outreach opportunities for members of the STU community in matters relating to research ethics

The policies and practices adopted by the STU REB will be consistent with the Tri-Council Policy Statement: "Ethical Conduct for Research Involving Humans" (current version).

Research Ethics Board Members, 2015-2016

Member	Representation	Expiration of
		Appointment
Chair: Karla O'Regan	Criminology/Legal	June 30, 2017
Brian Carty	Social Work	April 30, 2017
Erin Fredericks	Sociology	June 30, 2018
Michael George	Religious Studies	June 30, 2018
Claire Goggin	Criminology	June 30, 2018
David Korotkov*	Psychology	Aug 31, 2016
Sue McKenzie-Mohr	Social Work	Aug 31, 2016
Sharon Murray	Education	June 30, 2016
Alanna Palmer	Community	April 22, 2016
Nicholas Sehl	Community (Alternate)	Sept 30, 2017
Ray Williams	Education	April 30, 2017

^{*} An error was made in last year's reporting of Dr. Korotkov's membership term dates on account of Dr. Korotkov's sabbatical (from July 1, 2015 – December 31, 2015).

The REB's Community Representative, Alanna Palmer, resigned from the Board on April 22, 2015 after eight years of valued service. Nick Sehl will now assume the role and a search for an alternate Community member is underway.

New Members as of June, 2016: (pending appointment approval)

Arielle Dylan (Social Work) – for a three year term expiring in 2019. In addition to regular REB duties, Dr. Dylan will serve as a Chapter 9 advisor for applications involving research with Aboriginal and indigenous communities.

Amanda DiPaolo (Human Rights) – for a three year term expiring in 2019. Dr. DiPaolo will serve as a Humanities representative on the Board.

Sharon Murray has also agreed to a renewal of her membership term for a two-year period, expiring June 30, 2018.

General information

The University endorses the ethical principles cited in the Tri-Council Policy Statement and has mandated its Research Ethics Board (REB) to ensure that all research investigations involving human participants are in compliance with the Statement.

The STU REB has jurisdiction over all STU Research involving human participants. As per the REB Policy (see *Preamble*), "STU Research" is that which is conducted:

- by members of the STU community (including faculty, students, and staff)
- by researchers in formal collaboration with STU members (e.g. co-investigator from another university or organization); or
- at STU or otherwise through the STU community (e.g. recruitment from STU community)

All STU Research which involves human participants will proceed only after ethical approval has been granted by the REB or, in the case of undergraduate research that does not pose more than minimum risk to participants, by the Departmental Research Ethics Committees.

Activities of the REB in 2015-2016

1) Review of research ethics applications and management of active files

A central activity of the REB is reviewing research ethics applications presented by STU researchers and those wishing to conduct research within the STU community. All such research involving human participants must be approved by the REB before it can commence. During the last year (July 1, 2015 to June 30, 2016), the REB reviewed and **approved 32 files**. Also, 13 studies concluded and had their files closed and 32 files were renewed for another year. Finally, 1 file was refused ethics approval in October 2015.

The REB has **73 active research files**, which includes the administrative work of renewing and closing existing files, as well as ongoing consultation with researchers involved in existing projects.

In addition, the REB responded to a request by Dr. Catherine Gidney (October 18, 2015) for a review of her project funded by the Nova Scotia Health Research Foundation for the purpose of determining whether the project fell within one of the TCPS2's grounds for exemption from REB review (Articles 2.2 and 2.4). The project was found to fall within these Articles and thus deemed exempt from REB review. A letter outlining this decision was sent to the researcher and filed with the Office of Research Services on October 20, 2015.

2) The TCPS2 (2014): Policy Update & Professional Development

The Tri-Council Policy Statement on the Ethical Conduct for Research Involving Humans is the main document used to guide all activities, policies, and procedures of the REB. This year, a number of new measures have been taken to ensure familiarity and compliance with the new Policy Statement. These include:

a) CORE Tutorial Certification (ongoing)

Given how essential it is that all REB members become intimately familiar with the Tri-Council Policy Statement, as of June 30, 2015, all members of the STU REB were required to complete the TCPS2 CORE (Course on Research Ethics) tutorial and submit completion certificates to the Office of Research Services, via the implementation of an internal REB policy. This requirement was subsequently added to the REB's Senate Policy and approved at the June, 2016 Senate meeting. As of June 30, 2016, CORE completion certificates are on file for all currently serving members.

Also, as of June 16, 2016, all applications for ethical approval that are assessed as involving *more than minimal risk*, must be accompanied by a CORE completion certificate (Section 2.1, REB Senate Policy).

b) Senate Research Ethics Board Policy Update

Over the course of the last two years, the REB has undergone a substantial review of the 2011 Policy document and made a number of revisions, both with an aim for increasing clarity on the roles and responsibilities of the REB and for ensuring consistency with the TCPS2 (2014) and its current application standards. These revisions were submitted to Senate and were approved at the June 16, 2015 meeting. An executive summary of these changes can be found in Appendix A.

c) Professional Development

For the first time, the REB Chair and REB Co-ordinator attended the Public Responsibility in Medicine and Research (PRIM&R) Social, Behavioral, and Educational Research (SBER), November 2015 Conference in Boston MA. Sessions included "Strategies to Assess and Mitigate SBER Risk", "Changing Concepts of Anonymity, Confidentiality and Privacy in SBER" and "Flexibility and Innovations in SBER IRB Review Procedures". Key concepts were clarified and new concepts were brought back and presented to the STU REB. It was very informative to see how our system of national guidelines compares to the American legal-based approach to ethics review and a number of other university REBs have sought consultation with the STU REB regarding the content of this conference. Where budgets allow, the REB Chair would recommend future attendance at PRIM&R.

The second conference, hosted by the Canadian Association of Research Ethics Boards (CAREB) was held in Toronto in May 2016. The REB Chair, REB Co-ordinator, and REB Member Sharon Murray attended valuable sessions on the "Responsible Conduct of Research", "Vulnerable Populations", "Managing Risk While in the Field", "Enhancing Review of Research involving Gender Non-Conforming, Queer, and Trans Youth", and many others. Materials and new ideas were brought back to STU, generating several new projects and revisions to current procedures to both increase the

REB's effectiveness and to expand Faculty's understanding and application of TCPS 2 requirements.

In addition, the REB Coordinator has continued her studies in the 2-year certification course for Research Administrators offered through the Canadian Association for Research Administrators. Several sections of this course relate to research ethics, and the learning outcomes will serve both the Coordinator and board members. Coursework will conclude in September 2017.

3) Educational Outreach to STU Community

One of the key responsibilities of the STU REB, as outlined in Article 1.2 of the STU REB Senate Policy, is the participation and development of continuing education opportunities for the STU community. As part of this mandate, the REB Chair attended the meetings of the Department Chairs (Social Sciences, Humanities) on September 14, 2015 to discuss the role of the REB and its activities. Particular focus was placed on the scope and requirements of departmental ethics review committees. These points were summarized on a handout (see Appendix B) which was distributed at the meeting and made available electronically to the Deans for further reference.

The REB Chair also presented to the Administrative Management Committee (AMC) on April 28, 2015. This presentation highlighted the kinds of administrative activities which might trigger REB review alongside the TCPS2's grounds for REB review exemption. Documentation that was distributed at this meeting can be found in Appendix C.

Additional educational seminars were offered during both academic terms by the REB Chair to two Honours Seminar classes (CRIM 4006 and PSYC 4996) as well as a UNB Nursing course, during a practicum at the Fredericton Downtown Health Clinic in April, 2016.

4) Revising REB Forms

In 2016, the REB Chair and Co-ordinator reviewed and revised all REB forms, including the REB Application Form, the Renew/Close Form, and the Departmental Ethics Committee Annual Report Form. In addition, two new forms were created, namely the Amendment Request Form and the Unanticipated Issue Report Form. The REB Coordinator also worked to create online and interactive versions of these documents. These efforts were recognized by REB administrators from both UNB and CBU who contacted the office to comment on the forms and to learn how to incorporate our (JotForm software) innovations into their current form systems.

Plans for REB in 2016-2017

1) Review of research ethics applications and management of active files

The REB will continue the work of reviewing research files and consulting with STU researchers. To facilitate this process, a "reviewer checklist" has been designed which will guide individual REB members in their review of files as well as provide direction

for REB discussions of ethics issues during file reviews at the Board level. Once finalized, this checklist will be implemented starting in August at the first REB meeting, and will also be made available on the REB website as a tool for researchers as they prepare ethics applications.

2) TCPS2 (2014) Compliance

As part of the REB's ongoing efforts to ensure compliance with the new TCPS2 (2014), a number of review and revision processes are planned for the 2016-2017 year. These include continued amendments to our forms and updating the REB's Standard Operating Protocols (SOPs) in accordance with the revised REB Senate Policy. In addition, the Chair has recommended the appointment of a Chapter 9 advisor to the Board for guidance on applications involving research in Aboriginal and indigenous communities as well as the appointment of a representative from the Humanities faculty. The Chair will also be investigating the establishment of an ad-hoc Advisory Committee for the REB, made up of relevant experts from the University and wider community. These actions will continue St. Thomas University's adherence to the new TCPS2 (2014) requirements as well as our conformity to national research ethics practices and procedures.

3) Educational Activities & Professional Development

The REB plans to provide further opportunities for ethics education for its Board members as well as other members of the STU community through a variety of activities:

a) Presentation at the Fall, 2016 Chairs Meeting

Continuing with the practice established over the past two years, the REB Chair will once again request the opportunity to present to the Departmental Chairs at one of their monthly meetings in the Fall term. In addition to reviewing the procedures for departmental-level ethics review and reporting, some of the recent revisions to the REB's Senate Policy will be discussed in conjunction with distribution of the Executive Summary submitted to Senate in June, 2016 (see Appendix A) and the Panel on Research Ethics *Companion Document to the TCPS2 (2014)*. All materials will also be made available on the STU REB website.

b) Presentation at the Spring 2017 AMC Meeting

In keeping with the practice established this past year, the REB Chair will once again request the opportunity to present to the AMC Meeting in the spring, focussing on the scope of REB review, grounds for exemption, and reporting procedures.

c) Requested in-class Presentations, 2016-2017

The instructors for the Honours Seminars in the Criminology and Psychology Departments have already requested a presentation from the Chair during the upcoming academic year. In the case of PSYC 4996, two sessions have been requested for 2016-2017. The Chair has also been in talks with the School of

Social Work with respect to a presentation in two offerings of SCWK 5013 (Group Work Theory and Design).

d) REB & Researcher Professional Development and Educational Workshop

On August 11, 2016, the REB plans to host a full-day educational workshop on research ethics. Dr. Gordon DuVal, Chair of the National Research Council's REB, will deliver two morning sessions for members of the STU REB, covering "Chapter 9 - Research Involving Aboriginal People" and "Recruiting Vulnerable Participants on the Internet". The afternoon sessions will be open to all faculty, covering "The Scope of REB Review" and "Gathering Research Data While Instructing".

These topics were selected based on the results of an interest poll administered by the REB Coordinator in the Spring term, 2016.

e) Collaborative Ethics Policy with Journalism

The REB will continue its collaboration with the Office of Research Services and the Department of Journalism in establishing a university policy for research ethics compliance in journalistic research. In January, 2016, Dr. Stephen Ward (UBC) was contacted by Prof. Philip Lee for consultation and drafting of a set of ethical guidelines for STU Journalism students. This work is underway and will be reviewed by the REB as it develops.

f) CAREB and CARA Conferences Attendance

As in past years, participation at both the CAREB and CARA 2016/2017 conferences will be encouraged among all REB members (funds permitting) Where budgets allow, attendance at the PRIM&R 2016 conference will also be investigated given how valuable attendance in 2015 proved to be.

g) Regional Hosting

STU will be hosting CARA East/CAREB Atlantic for the second time (hosted in 2013) with two half-days of keynotes and sessions focused on research ethics, open to all REBs in the Atlantic Provinces.

4) REB Administration

To facilitate a more equitable and efficient file review process, the REB will continue to seek to establish the position of "Vice-Chair" in this upcoming year. This is a position that is common to many other REBs in Canada and ensures a more coherent transition process between Chair terms.

Research Ethics Board Policy

Approved by Senate, June 2005

Revised and approved by Senate, June 2016

Preamble

St. Thomas University endorses the principles set out in the "**Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans**" (current version). This document describes how the University will apply the Tri-Council Policy Statement (TCPS). This policy has been worded using the language employed in the TCPS2 (2014). All references to the TCPS should be read in accordance with its most current version.

Research is an essential component of the mission of St. Thomas University and some of this research involves studying human participants. The University has a responsibility to engage in research advancing human knowledge. The use of human beings in the conduct of research confers responsibilities to the investigator(s). It is also the responsibility of the University to promote ethical research.

This policy is intended to ensure that the highest ethical standards in the conduct of research involving human participants are maintained at St. Thomas University in compliance with the Tri-Council Policy Statement. These ethical standards include the core principles of 1) respect for persons, 2) concern for welfare, and 3) justice.

A fundamental premise of the TCPS is an understanding that research can benefit human society. Academic freedom is a key component to this endeavour. University researchers must have freedom of inquiry, the right to disseminate the results of that inquiry, freedom to challenge conventional thought, freedom from institutional censorship and the privilege of conducting research on human participants with the trust and support of the general public, often with public funding. With these freedoms come responsibilities to ensure that research involving human subjects meets high scholarly and ethical standards, is honest and thoughtful inquiry, involves rigorous analysis and complies with professional and disciplinary standards for the protection of privacy. Review of research proposals by the REB takes into account these freedoms and responsibilities and provides accountability and quality assurance both to colleagues and to society.

1.0 Terms of Reference

1.1 Scope

Review is available normally only to members of the STU community, external researchers working in formal collaboration with STU members, or for research conducted at STU by others (UNBF researchers see Appendix A). For the purposes of this policy, the term "STU Research" is used to refer to all three categories of research.

All research projects involving human participants undertaken by members of the university community fall within the jurisdiction of the STU Research Ethics Board. This includes all research conducted by STU faculty, staff and students, including students carrying out research as part of class assignments, irrespective of the source of financial support (if any) and irrespective of the location of the project, provided the investigator represents the work as STU Research.

In some instances, ethical review of student work may be conducted at the departmental level (see Section 2.7). Researchers from outside the community who access resources or participants at STU are also required to undergo review. Review by the Research Ethics Board is also necessary for research involving human biological materials as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells.

The term "Research" is defined in the TCPS as "an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation" where a "disciplined inquiry" refers to "an inquiry that is conducted with the expectation that the method, results, and conclusions will be able to withstand the scrutiny of the relevant research community" (Article 2.1). This does not normally include quality assurance studies, quality improvement studies, program evaluation activities, performance reviews, creative practice activities, or testing within the normal educational requirements (Article 2.5). Other research that is exempt from REB review is outlined below in Section 2.2 of this Policy).

Researchers who are unsure if their project falls within the scope of REB review should contact the REB Chair for guidance.

1.2 Responsibilities

St. Thomas University Research Ethics Board (REB) is responsible to the President or their designated representative through the Associate Vice-President (Research) of St. Thomas University for:

- developing policies regarding ethical issues relating to the use of human participants in research;
- reviewing all protocols requiring the participation of human participants for ethical approval;
- reviewing annually all policies regarding ethical issues relating to the use of human participants in research projects to ensure that policies remain current;
- dealing with matters concerned with human-based research referred to the REB by the President or their designate of STU;
- monitoring ongoing research and terminating any project that does not conform to ethical standards:
- responding to inquiries from external agencies with responsibility to monitor ethics review procedures at the University;
- preparing an annual report for submission to the President or their designate;
- participating in continuing education in matters relating to ethics and the use of human participants;
- organizing educational outreach opportunities for members of the STU community in matters relating to research ethics

The policies and practices adopted by the STU REB will be consistent with the Tri-Council Policy Statement: "Ethical Conduct for Research Involving Humans" (current version).

1.3 Composition of the REB

The REB shall be made up of no less than 5 members, including both men and women, and will include:

- At least one community representative with no formal affiliation with the University
- A minimum of two university members with broad expertise in the methods or in areas of research covered by the REB in different disciplines.
- At least one university member with broad knowledge in ethics or experience in the evaluation of ethical implications of research involving human participants.
- At least one member capable of alerting the REB to legal issues and their implications in relevant areas of research.

Substitute members may be appointed at the discretion of the President or their designate. Substitute members can be called in to replace regular members unable to attend or to provide expertise in a specific area.

Ad Hoc Advisors will be consulted in the event that the board lacks specific expertise or knowledge to review the ethical acceptability of a research proposal competently.

The balance and composition of the university members on the REB shall be the purview of the President of STU or their designate.

Board members shall serve for three-year terms, which normally may be renewed once. Appointments can range from one to four years to allow for continuity of membership. Members will be selected in accordance with Tri-Council Policy. To be eligible for REB membership, completion of the TCPS2 CORE Tutorial is required.

1.3.1 REB Chair

In order to be appointed Chair, the faculty member must have either served on an REB for a minimum of three years or have sufficient experience in the field of ethics.

A Chair is recruited either by the President or their designate through informal communication, or through the volunteering of a current or former member of the REB.

The President or their designate shall appoint one current or former member of the REB to serve as Chair for a three year (renewable) term.

The REB Chair is responsible for ensuring that the REB review process conforms to the requirements of the TCPS, and must provide overall leadership for the REB.

1.4 Meetings

The REB shall meet regularly to review submissions. In the event of a tie vote, the matter under consideration will be considered not passed.

The REB shall require a quorum of at least the majority of its members (not including substitute members) at all meetings concerned with the ethical approval of research proposals. In addition, it is necessary to have at least one community member present and it is necessary to have one member capable of alerting the board to the legal issues. When there is less than full attendance, decisions requiring full review should be adopted only when the members in attendance at that meeting have the specific expertise, relevant competence and knowledge necessary to provide an adequate research ethics review of the proposals under consideration.

Meetings are not required in the case of delegated review. An annual schedule of REB meetings will be published online.

1.5 Authority

The University endorses the ethical principles cited in the Tri-Council Policy Statement and has mandated its Research Ethics Board (REB) to ensure that all research investigations involving human participants are in compliance with the Statement.

St. Thomas University, by and through the University Senate, has mandated the REB to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human subjects which is conducted within, or by members of, the University, using the considerations set forth in TCPS2 as the minimum standard.

The University may not override negative REB decisions reached on grounds of ethics except in accordance with the formal appeal mechanism specified in section 3.2, below. This does not interfere with the University's ability to refuse to allow certain research within its jurisdiction, even though the REB has found it ethically acceptable.

The STU REB will have jurisdiction over all STU Research involving human participants. Proposed studies will proceed only after ethical approval has been granted by the REB or, in the case of minimal risk undergraduate research, the appropriate departmental Research Ethics Committee (see Section 2.7).

The STU REB also has the authority to establish its own procedures and internal policies that do not conflict with those established by the University Senate or the TCPS (current version) and to make recommendations to Senate for revisions to this and other Policies.

2.0 Procedural Guidelines for the Review of a Research Proposal

2.1 Submission

The basic principle is that all "STU Research" (as defined in Section 1.1 of this Policy) comes under the jurisdiction of the REB. This refers to research involving human participants undertaken by members of the university community -- including all faculty, visiting researchers, students, and staff -- irrespective of the source of financial support (if any) and irrespective of the location of the project. While it is not necessary for the REB to review a proposal before it is submitted to a funding agency, REB approval must be obtained before the work begins and funds are released.

Visiting researchers should contact the STU REB well in advance of the anticipated start date of research. Submissions for review should be submitted to the STU REB using the "Application for Review of Research Involving Humans" form (available on the REB website). Where the proposed project is assessed as involving more than minimal risk, the REB application must be accompanied by a completion certificate for the TCPS Course on Research Ethics (CORE).

2.2 Exemption from Ethics Review

All STU Research that involves living human participants requires review and approval by the REB in accordance with this Policy, before the research is started, except as stipulated below:

- a) Research that relies exclusively on publicly available information (Article 2.2). For instance, research about a living individual involved in the public arena, or about an artist, based exclusively on publicly available information does not require review. Such research only requires ethics review if the subject is approached directly for interviews or for access to private papers, and then only to ensure that such approaches are conducted according to professional protocols.
- b) Research involving naturalistic observation of people in public places where the research does not involve any intervention by the researcher or direct interaction with the individuals or groups being observed; the individuals or groups targeted for observation have no reasonable expectation of privacy; and dissemination of research findings will not allow for the identification of individuals (Article 2.3).
- c) Research that relies exclusively on secondary use of anonymous data (Article 2.4).
- d) Quality assurance studies, quality improvement studies, program evaluation activities, performance reviews, creative practice activities and testing within the normal educational requirements (Article 2.5).

2.3 Scholarly Review

a) In the case of research proposals that present more than minimal risk,, the design of the project must be peer reviewed to assure that it is capable of addressing the question(s) being asked in the research and that the researcher has the experience and competence to conduct the inquiry. "Minimal Risk" is defined in the TCPS2 (Chapter 2, Section B) as "research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research).

Risks in research are not limited to participants. In their conduct of research, researchers themselves may be exposed to risks that may take many forms (e.g., injury, incarceration). Risks to researchers may become a safety concern, especially for student researchers who are at a learning stage regarding the conduct of research, and who may be subject to pressures from supervisors to conduct research in unsafe situations.

Sufficient peer review may be considered to be any one of the following:

- i. Successful approval by the REB (if research is in the REB's field of expertise).
- ii. Successful funding of a grant proposal by a funding agency.
- iii. Ad hoc independent external peer review reporting directly to the REB.
- b) The extent of the review for scholarly standards that is required for biomedical research that does not involve more than minimal risk will vary according to the research being carried out.
- c) Research in the humanities and the social sciences which poses no more than minimal risk shall not normally be required by the REB to be peer reviewed.
- d) Certain types of research, particularly in the social sciences and the humanities, may legitimately have a negative effect on public figures in politics, business, labour, the arts or other walks of life, or on organizations. Such research should not be blocked through the use of risk/benefits analysis or because of the potentially negative nature of the findings. Such research should be carried out according to the professional standards of the relevant discipline(s) or field(s) of research.

2.4 Principle of Proportionate Review

The REB will use a proportionate approach such that the level of review is determined by the level of risk it poses to the participants: the lower the level of risk, the lower the level of scrutiny (delegated review); the higher the level of risk, the higher the level of scrutiny (full board review). A proportionate approach to assessing the ethical acceptability of the research, at either level of review, involves consideration of the foreseeable risks, the potential benefits and the ethical implications of the research.

2.5 Normal Review Process

The REB shall normally meet face to face in order to review submitted research proposals.

In some cases, the REB may invite researchers to a review meeting in order to consider the ethical solutions proposed by researchers for problems arising in their studies. The REB shall accommodate reasonable requests from researchers to participate in discussions about their proposals, but the researchers must not be present when the REB is making its decision. REB Meeting Minutes are confidential and are kept by the REB Coordinator for insertion into the appropriate case files.

The REB shall keep a confidential "open file" in a secure place in the Office of Research Services for researchers applying for ethical approval. The file shall be opened by the Chair when sufficient information has been submitted by the researcher to start the review process. The original application, descriptions of research and methodology, correspondence, relevant documents, ethical certificates, revised materials, and any comments from the public or other information relevant to the research project shall be kept in the file. It is the responsibility of the researcher to address all the recommendations made by the REB and keep the file complete and up to date at all times.

When the research project is finished, and the researcher(s) notifies the the REB of the study's completion, the file shall be "closed" but kept as a record of TCPS compliance. The files remain the property of STU and cannot be removed from the Office of Research Services by the researchers. These files shall be subject to audit by authorized representatives of STU, members of Appeal Boards, and funding agencies.

All research receiving ethical approval, whether through the normal or delegated process (Section 2.6), as well as that receiving departmental level review (Section 2.7) shall require a proper file showing compliance with the Tri-Council Policy Statement.

Insufficient information in the file is grounds for refusing or delaying ethical approval.

2.6 Delegated Review

Delegated review does not require a meeting of the full REB. It can usually be completed within two weeks of submission of a completed application form. The Chair must report requests for delegated review and results of such reviews to other members of the REB at the next meeting of the full Board. The researcher must specifically request delegated review and the REB Chair may reject any application for delegated review and refer it to the REB for full review if needed. Delegated review is a review by the Chair of the REB and at least two other members of the REB. It is available only in cases which fulfill one of the following criteria:

- a) The research that is confidently expected to involve only minimal risk (as defined in Section 2.3 of this policy and in Chapter 2, Section B of the TCPS). The researcher is responsible for an acknowledgement of the project's minimal risk to the REB and an explanation thereof;
- b) Research projects which have already received approval by the STU REB, have complied fully with any requirements, have an up-to-date file, and the applicant is simply renewing the ethical approval certificate without significant changes to the ongoing research process;
- c) minimal risk changes to already approved research; or
- d) annual renewals of approved minimal risk research;
- e) annual renewals of more than minimal risk research where the remaining researchattributable risk is minimal (e.g., the research will no longer involve new interventions to current participants and no additional participants will be enrolled in the study'
- f) annual renewals of more than minimal risk research in which there has been:
 - i. no significant changes to the research,
 - ii. no increase in risk to (or other ethical implications for) the participants since the most recent review by the full REB, and

iii. the REB Chair has determined that the delegated review process is appropriate.

2.7 Departmental Level Review

This policy requires that all Faculty research must be submitted to the REB. If, however, a study is a teaching exercise (e.g., part of an undergraduate course and/or Honour's project), and entailing *no more than minimal risk*, it should be reviewed by the Departmental Research Ethics Committee on behalf of the REB and in compliance with the Tri-Council Policy Statement.

The Department must report results of such reviews to the REB at the end of the academic year. Where no ethics committee exists at the departmental level, the Department Chair should contact the Chair of the REB for guidance. Ad-hoc Departmental Research Ethics Committees may be formed at the discretion of the Chair of the REB for the purposes of conducting a departmental level review.

Student research deemed to be beyond minimal risk must be reviewed by the REB. Student research (of any risk level) that forms part of a faculty member's own research program should be reviewed by the REB.

2.8 Continuing Ethics Review

- a) Ongoing research shall be subject to continuing ethics review. The Chair of the REB must be promptly notified of any substantial change to the research plan or research protocol. Researchers must report without delay to the REB any unanticipated issues or events that have or may increase the level of risk to participants, or that have other ethical implications.
- b) Researchers will be asked to include monitoring mechanisms by which the public participating in the research may contact the Chair of the REB. Problems or complaints will be taken seriously by the REB and researchers may be asked to modify their studies in view of such complaints.
- c) Ethics certificates are issued for one year. If the project continues after one year the researcher must submit a completed "Annual/Final Report on Research Involving Humans" Form" to the REB. If no substantial change has been made to the research plan or research protocol, the Chair of the REB may issue a one-year extension. If, in the opinion of the REB Chair, the research plan or research protocol has been substantially changed, re-submission and review by the REB may be required.
- d) Annual renewals of ethics certificates are limited to a five year maximum. If the study is to continue beyond 5 years, a review of the study's protocols, through a full REB or delegated review (based on level of risk), must be conducted.
- e) The REB shall be promptly notified by the researcher when the project concludes by completing the "Annual/Final Report on Research Involving Humans" Form. A project is considered "concluded" when both data collection and data analysis have ceased.

2.9 Conflicts of Interest

2.9.1 Research Ethics Board Members

The TCPS2 requires that REB members "disclose real, potential or perceived conflicts of interest to the REB" (Article 7.3). If an REB is reviewing research in which a member of the REB has a personal or financial interest in the research under review (e.g., as a researcher or as an entrepreneur) or any other real or perceived conflict of interest (as defined in Chapter 7, Section A of the TCPS2) the member should not be present when the REB is discussing or making its decision. In cases of disagreement over conflicts of interest, both the REB member in alleged conflict and the researcher may present evidence and offer a rebuttal concerning the nature of the conflict of interest. The Chair of the REB has the final decision regarding how to proceed.

2.9.2. Researchers

As per Article 7.4 of the TCPS, researchers shall disclose any real, potential or perceived conflicts of interest in the research proposals they submit to the REB, as well as any institutional conflicts of interest of which they are aware that may have an impact on their research. Upon discussion with the researcher, the REB shall determine the appropriate steps to manage the conflict of interest.

2.9.3 Institutional

St. Thomas University respects the autonomy of the Research Ethics Board and recognizes that the REB must have the appropriate financial and administrative independence to fulfil its duties. For the integrity of the research ethics review process, and to safeguard public trust in that process, the University shall ensure that the REB is able to operate effectively and independently in their decision making, free of inappropriate influence, including situations of real, potential or perceived conflicts of interest.

3.0 Decisions of the Research Ethics Board

3.1 Reconsideration

Researchers have the right to request, and the REB has an obligation to provide, reconsideration of decisions affecting a research project. When the REB is considering a negative decision, it shall provide the researcher with all the reasons for doing so and give the researcher an opportunity to reply before making a final decision.

The President of STU or their designated representative may not override negative REB decisions reached on grounds of ethics without a formal appeal mechanism.

3.2 Appeal

Researchers must apply to the President or their designated representative to appeal a negative REB decision within two months of the date of the decision. A copy of the appeal letter should also be sent to the REB Chair. STU shall use a duly constituted REB from another institution as its Appeal Board. Non-compliance with the substance of the

Tri-Council Policy Statement is a reason for refusing to grant an appeal. Appeals may be granted only on procedural grounds or when there is a significant disagreement over an interpretation of the Tri-Council Policy Statement. The decision of the Appeal REB shall be final and binding.

4.0 Report of the Research Ethics Board

Certificates of Ethical Approval, signed by the Chair of the STU REB will be issued to the

Principal Investigator(s) and the Associate Vice-President (Research). Certificates will also be available to the President or their designated representative and Vice-President (Academic & Research) through the Office of Research Services.

Any decisions by the Chair to approve minor amendments without full committee review will be reported to the REB, recorded in the minutes, and included in the researcher's open file.

An annual activity report from the REB will be made to the President or their designated representative through the Office of the Associate Vice-President (Research) who will in turn bring the report to Senate for consideration.

5.0 Multi-jurisdictional Research

Given that all Universities in Canada that receive funding from SSHRC, CIHR and NSERC must abide by the Tri-Council Policy Statement (TCPS2), and in accordance with the principle of proportionate review from the TCPS2, the following alternative review models avoid "unnecessary duplication of review without compromising the protection of participants" (TCPS2, Article 8.1).

Chapter 8 (Multi-jurisdictional Research), Article 8.1 from the TCPS2 states that "An institution that has established an REB may approve alternative review models for research involving multiple REBs and/or institutions, in accordance with this Policy."

Following Article 8.1 of the TCPS2, the STU REB creates one alternative review model that will not require a STU researcher to submit his/her study for regular ethics review at STU or continuing ethics review at STU as long as all the following criteria are met:

- 1. The study will not be conducted at STU
- 2. The study is considered minimal risk*
- 3. The STU researcher is not the principal investigator
- 4. The STU researcher provides the STU REB with documentation showing that the study has been approved by the REB of the principal investigator's institution
- 5. The study in question has been reviewed and approved by a Canadian REB that adheres to the TCPS

The STU REB has authority to determine if these criteria have been satisfactorily met. If any criteria are not met, the researcher must submit his/her study to the STU REB for

review. Further, if a study meets the above requirements and has been approved by the STU REB, the STU researcher is still obligated to inform the STU REB Chair of any ethical problems that arise in or from the study.

*As defined in Chapter 8, Section B of the TCPS2 (current version). To determine if a study is minimal risk, the researcher must provide the STU REB Chair with all relevant information to make that determination, including an explanation of the researcher's own designation of the risk level.

6.0 Administration

6.1 Administrative Support

The work involved in the ethical review process should be distributed appropriately among faculty members, staff, researchers, and administrators.

The Associate Vice-President (Research) will provide administrative support to the REB including:

- Distribution of forms and materials necessary for submission of research proposals to the
- RFB
- Collection of submissions and distribution of submissions to REB members
- Keeping minutes of REB meetings
- Storing submissions and related materials in a secure location
- Supporting the REB in its educational activities
- Acting as the point of contact for the Tri-Council Advisory Group
- Other duties related to the support of the REB in carrying out its mandate

Chairs and Directors of Programmes will provide significant support to the REB, with respect to:

- Educational activities
- Management of the system for reporting research
- Ensuring that researchers requiring ethical review are submitting their projects to the
- REB
- Establishing departmental-level ethical review committees as needed
- Advising their faculty members about the need to comply with the Tri-Council Policy Statement.

Departments should screen student applications for ethical review prior to submission to the REB. The REB may return applications to the department if they do not conform to the requirements of the Tri-Council Policy Statement. Individual departments are also expected to support and train students so that undergraduate and graduate research projects are ethical, and those that exceed minimal risk may be efficiently reviewed by

the REB. To this end, the REB recommends completion of the TCPS2 CORE tutorial (available online: https://tcps2core.ca/).

6.2 University Support

STU shall provide adequate resources and an annual budget to support the administrative processes and educational activities required by the REB so that the University as a whole remains in compliance with Tri-Council policy. The REB will have access to a legal expert (other than the University's legal counsel) knowledgeable in the applicable law.

6.3 Sanctions

The REB Chair shall have the sanction of refusing permission to open a research account or access university controlled funds for researchers who do not comply with the Tri-Council Policy Statement.

The REB will report to the President or their designated representative through the Associate Vice-President (Research) any cases which undermine STU's compliance with the Tri-Council Policy Statement and the President or their designated representative shall decide if and/or what sanctions or penalties to impose on the researcher(s), including, but not limited to, those outlined in the University's policy on research integrity.

Appendix A

A reciprocal agreement between STU and UNBF for the recruitment of research participants in minimal risk research has been reached. UNBF researchers wishing to recruit participants at STU (e.g., via poster, email, or webpost), are to submit their UNBF REB application and certificate to the STU REB. The STU REB will then approve, if appropriate, the recruitment of participants from the STU community, subject to modifications if necessary. A STU REB number will be assigned to the approved application, and the application will be kept on file. The same procedure would apply for STU researchers wishing to recruit participants at UNBF.

REB Policy Companion Document Executive Summary of Revisions

June 14, 2016

Aside from editorial changes (e.g. "Associate VP (Research)" in lieu of "Dean of Research") and updated references to Articles within the TCPS 2 (2014), there are 8 areas of substantive changes to the Senate policy to bring the University in line with the TCPS2 (2014). These are:

- 1. An addition to the Preamble to include <u>a recognition of academic freedom</u>. (Language taken directly from TCPS2 (2014) Ch.1, Section A).
- 2. Update of <u>definitions and key terms</u> to include TCPS2 2014 elaborations. This includes clarification and/or expansion within the STU Policy of the following terms:
 - "research" (for the purposes of REB review), including a definition of the term "disciplined inquiry" (used in TCPS2 definition of 'research') **Section 1.1**
 - "minimal risk" (as per TCPS2 Chapter 2 revisions) Section 2.3(a)
 - "proportionate review" Section 2.4
 - "conflict of interest" Section 2.9
- 3. Changes to Terms of Reference:
 - Responsibilities of the REB (bullets 5 and 6) **Section 1.2**
 - Process of making appointments to the Board Section 1.3
 - CORE tutorial requirement for all REB members **Section 1.3**
 - Renewable term for REB Chair Section 1.3.1
 - Clarification of Institutional Conflicts of Interest Section 1.5
- 4. Revised Procedural Guidelines for the Review of a Research Proposal:
 - CORE tutorial requirement for all applicants with research identified as above minimal risk – Section 2.1
 - Clarification of grounds for exemption from REB Review (now found in its own policy section) – Section 2.2
 - Expanded criteria for Delegated Review Section 2.6 (e-f)
 - Clarification of departmental level review committee process (including criteria for which applications can be screened at the departmental level) – Section 2.7
 - 5-vear maximum period for annual renewals Section 2.8(d)
 - Clarification of when a file is considered "concluded" Section 2.8 (e)
- 5. Added under <u>Multi-jurisdictional Research</u>, the inclusion of researcher's own designation of the risk level **Section 5.0**
- 6. Clearer statement on the establishment of departmental-level ethical review committees **Section 6.1**
- 7. New CORE tutorial *recommendation* for student research projects that exceed minimal risk **Section 6.1**
- 8. Reference to STU's Research Integrity Policy Section 6.3



Research Ethics Board

Presentation to Chairs & Directors Meeting September 14, 2015

Upcoming REB Meetings

September 22 September 8 deadline to submit REB applications for full-board review

October 13 September 29 deadline to submit REB applications for full-board review

November 17 November 3 deadline to submit REB applications for full-board review

- Applications received after the submission deadline may not be reviewed until the following month, but the board will make every effort to review late submissions.
- If needed, applicants may request an expedited review (Chair and at least one other member conducts the review). Expedited reviews typically take 2 weeks to complete.

REB Membership

Brian Carty, Social Work
Erin Fredericks, Sociology
Michael George, Religious Studies
Clare Goggin, Criminology & Criminal Justice
Sue McKenzie-Mohr, Social Work
Sharon Murray, Education
Karla O'Regan, Criminology & Criminal Justice, REB Chair
Alanna Palmer, Community Member
Nick Sehl, Community Member
Ray Williams, Education

Danielle Connell, REB Coordinator

Contact

REB Coordinator 452-0647 <u>reb@stu.ca</u> REB Chair 460-0347 <u>oregan@stu.ca</u>

Information

- Bound copies of the TCPS 2 are available in the ORS
- TCPS 2 CORE Tutorial is available online at https://tcps2core.ca/welcome
- STU REB website http://w3.stu.ca/stu/research/ethics



Research Ethics Board reb@stu.ca

FREQUENTLY ASKED QUESTIONS

1. What is the TCPS (or Tri-Council Research Ethics Policy)?

The <u>Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans</u> (or TCPS2, as it is commonly known), describes the policies of the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC) to promote ethical research involving human participants. These Agencies will consider funding (or continued funding) only to individuals and institutions that certify that they comply with this Policy Statement. Researchers should review this document before submitting an application to the REB. Bound copies of the <u>TCPS 2 (2014)</u> can be obtained through the Office of Research Services.

To learn more, consider taking the TCPS2 CORE (Course on Research Ethics) online tutorial.

2. What kinds of research activities require REB approval prior to be conducted?

St. Thomas University's REB Policy applies to all "STU Research." This means all research involving human participants that is conducted:

- by a STU staff or faculty member
- in formal collaboration with a STU staff or faculty member
- at STU (or with members of the STU staff, faculty, and student communities) by others
- by STU students as part of class assignments, teaching exercises, or honours projects

Research conducted by students that falls below minimal risk (see FAQ #10) should be reviewed by the appropriate departmental research ethics committee (see FAQ #4).

3. Which research projects do not require STU REB approval?

The TCPS2 provides REB exemption for research that is based on publicly available information (Article 2.2), non-intrusive observation in public places (Article 2.3), exclusively secondary use of data (Article 2.4), and/or is conducted purely for internal quality assurance, program evaluation, or educational testing purposes.

This means that research that is archival (i.e., uses only existing public or published records and materials) does not typically require ethics approval, nor do quality improvement studies, performance reviews, creative works, institutional evaluation activities, or testing exercises within normal educational requirements.

Work undertaken by undergraduate students as part of a formal course requirement does not need REB ethics approval as long as it poses no more than minimal risk to participants. The instructor of the course, however, must obtain departmental level ethics approval for student projects that involve research with human participants (including honours thesis research). If, however, the research undertaken involves *more than minimal risk*, REB approval is needed, regardless of who is conducting the research.

4. What is a Departmental Research Ethics Committee (REC)?

It is a committee at the departmental level that serves to review all research involving human participants that is conducted by students within the Department that falls below minimal risk. The REC should be composed of at least two departmental members (who have ideally completed the CORE Tutorial) and who are not in a conflict of interest in terms of the projects being reviewed. The REC should not be chaired by the Department Chair. Departmental RECs are required to report annually (in May) to the REB on the review processes and outcomes conducted throughout the year. RECs may also consult with the REB Chair on difficult or more complex issues. See the STU REB Policy (Section 2.7) for more information on departmental RECs.

5. How do I apply to the REB?

Please complete the <u>application form</u> and submit it either online or to the REB Coordinator, Danielle Connell in Brian Mulroney Hall room 312 (452-0647) or reb@stu.ca.

6. When should I apply?

During the teaching terms, you should ensure that your complete application is received by the Office of Research Services no later than the **first Monday of the month**. There are no deadlines for application during the summer months (May-August).

The review process takes time and may result in requests for clarification, amendments, or resubmission. It is always best to start the review process as early as possible in the development of a research project. Researchers should also feel free to contact the REB Chair to discuss any aspects of the application process prior to submission.

Some funding agencies require that ethics approval accompany the application. Other funding agencies receive applications before ethics approval is in hand as long as evidence is provided that the work has been or will be submitted for REB review. Although St. Thomas University allows submission of research proposals to funding agencies prior to ethics approval being issued, **in no case can research involving humans proceed without ethics approval**. Regardless of the source of funds, a St. Thomas University research account will not be opened to receive funds before ethics approval has been issued.

7. When does the REB meet?

The REB committee typically meets to review files every third week of the month (except December and May-August).

8. How are applications processed?

During the teaching terms, reviews are normally conducted by the full board during monthly meetings. During holiday seasons, reviews of projects deemed by the REB to be of minimal risk (see FAQ #10) typically undergo delegated review (sub-committee) rather than full board review.

9. When should I receive feedback from the REB after my application has been reviewed?

You will normally receive feedback within two weeks after the monthly REB meeting at which your application was discussed. Final approval may be immediate or may take a bit longer depending on whether you need to meet any requirements of the Board.

10. How do I know if my project is minimal risk or not?

"Minimal Risk" is defined in the TCPS2 (Chapter 2, Section B) as "research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research). In other words, where a person's participation in the research poses no more risks than what s/he would experience in a regular day, the research can be said to be of **minimal risk**.

Ultimately, the decision on the level of risk rests with the Board, but you should do your best to assess your project's degree of risk to human participants and communicate the basis for this assessment in your application. After all, no member of the REB will know your research better than you, so thinking through the kinds of experiences you anticipate your participants will have will help to determine the risks the research raises. No matter what the level of risk, focus your application for approval on making it clear to the Board how you are ensuring that the TCPS2 ethics requirements are being met in your project.

11. I am conducting research in another country. Is my STU research ethics approval all I need?

No, you may need to obtain approval from an institution in that country. Please make sure that any relevant certifications are obtained in that jurisdiction.

12. I am involved in a project with researchers at other institutions who have already received ethical approval from their respective REBs. Do I still need to apply to the STU REB?

Yes, however, the process is simplified. If you are in collaboration with another researcher in a study that has already received ethical approval from another university or institutional review board, you may be eligible for multi-jurisdictional review, provided that:

- o The study will not be conducted at STU (e.g. recruiting students)
- o The study is considered minimal risk
- The STU researcher is not the principal investigator

If all of these conditions are met, STU REB approval can normally be granted once documentation showing that the study has been approved by the REB of the principal investigator's institution (which adheres to the TCPS2) has been submitted to the STU REB.

13. When does REB-approved research no longer require ongoing REB review?

The TCPS does not make a determination regarding the stage at which REB review and approval would no longer be required. Typically, the end of the project can be defined as the point after which there is no further contact between the researcher and the participants, for example, at the end of data collection. Or, it could be after the data has been analyzed, in case some follow-up contact with participants is needed. In other cases though, REB approval should be maintained until after dissemination. The REB will determine the approximate end date for each file, taking into consideration the level of risk to participants as well as the type of research design (short term project, longitudinal research, research with reporting-back requirements, etc.); however, any guidance from the researcher in making this determination is very helpful.

14. Who can I talk to about other questions I have about research ethics?

Feel free to contact the Chair of the Research Ethics Board, Dr. Karla O'Regan (460-0437 or or or or the REB Coordinator, Danielle Connell (452-0647 or reb@stu.ca).



Research Ethics Board

AMC Presentation, April 28th, 2016

What kinds of research activities require ethical review prior to be conducted?

St. Thomas University's REB Policy applies to all "STU Research." This means all research *involving human participants* that is conducted:

- by a STU staff or faculty member
- in formal collaboration with a STU staff or faculty member
- at STU (or with members of the STU staff, faculty, and student communities) by others
- by STU students as part of class assignments, teaching exercises, or honours projects

Research in the fourth category (i.e. conducted by students as part of a course requirement) that <u>falls below minimal risk</u> should be handled at the departmental level. This is provided for in Section 2.7 of the REB Policy.

Departmental Research Ethics Committees (RECs):

- composed of at least two members (who have ideally completed the CORE Tutorial) and who are not in a conflict of interest in terms of the projects being reviewed
- may not be chaired by the Department Chair
- review all research conducted by students within the Department that falls below minimal risk
- report annually (in May) to the REB on review processes and outcomes conducted throughout the year
- may consult with the REB Chair on difficult or more complex issues

What does "minimal risk" mean?

"Minimal Risk" is defined in the TCPS2 (Chapter 2, Section B) as "research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research). In other words, where a person's participation in the research poses no more risks than what s/he would experience in a regular day, the research can be said to be of **minimal risk**.

Ultimately, the decision on the level of risk rests with the Board, but you should do your best to assess your project's degree of risk to human participants and communicate the basis for this assessment in your application. After all, no member of the REB will know your research better than you, so thinking through the kinds of experiences you anticipate your participants will have will help to determine the risks the research raises. No matter what the level of risk, focus your application for approval on making it clear to the Board how you are ensuring that the TCPS2 ethics requirements are being met in your project.

Exemptions from Ethical Review:

Not all research activities undertaken by STU community members will trigger an ethical review. The TCPS2 provides exemption for:

Publicly available information (Article 2.2)
Observation in public places (Article 2.3)
Secondary use of data or biological materials (Article 2.4)
Quality assurance/improvement studies or program evaluation (Article 2.5)

These exemptions apply to:

- Research based on existing information in the public domain (e.g. news articles, Statistics Canada surveys). <u>However</u>, if data can be used to identify specific individuals in ways that are not already public knowledge, the exemption may not apply.
- Observational research that studies human behaviour under natural circumstances (e.g. shoppers in a mall, hockey fans in an arena, discussants in an online forum). The observational research must not involve:
 - o any staged interventions or direct interactions with those being observed;
 - o reasonable expectations of privacy on the part of those observed;
 - o the identification of specific individuals in any disseminated results
- Studies conducted for the internal use of the University (e.g. quality assurance, performance reviews) or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes. <u>However</u>, if the data are later used for research purposes or wide dissemination of results, the project may require REB review.
- The gathering of **information for purposes other than research** (e.g. school records, online opinion sites) **that is later discovered to have research value**. Data files or samples from one study may be useful for other research purposes on their own or when combined with information from another study. This "secondary use of data" does not require REB review as long as:
 - o the data or samples are anonymous; and
 - o there is no way the data can be linked to the individuals who provided it;
 - o and not follow-up contact with the original study's participants occurs

CORE Tutorial:

Provides an applied approach to the TCPS 2. An 8-module, self-paced course featuring interactive exercises and multi-disciplinary examples – many of which employ current or well-known events that trigger ethical issues. Comes with a certificate of completion.

http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/

Contact us:

Karla O'Regan, REB Chair (<u>oregan@stu.ca</u>)

Danielle Connell, REB Coordinator (<u>reb@stu.ca</u>)

Research Ethics Board T. 506.452.0621