

St. Thomas University
Research Ethics Board
Annual Report 2017-2018

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Research Ethics Board Annual Report 2017-2018

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Responsibilities of the Research Ethics Board

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 1, 2017 to June 30, 2018.

The responsibilities of the St. Thomas University Research Ethics Board (REB) are outlined in Article 1.2 of the *St. Thomas University Research Ethics Board Policy* (see Appendix A). It reads as follows:

“The St. Thomas University Research Ethics Board (REB) is responsible to the President 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 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, 2017-2018

Member	Representation	Expiration of Appointment
Erin Fredericks	Sociology	June 30, 2018
Claire Goggin	Criminology	June 30, 2018
Beth Lyons	Community Rep	June 30, 2020
Sharon Murray	Education	June 30, 2018
Karla O'Regan, Chair	Criminology	June 30, 2018
Nicholas Sehl	Community Rep	Sept 30, 2020

New Members as of July 1, 2018:

Martin Kutnowski (Fine Arts) – for a three-year term expiring June 30, 2020

Mihailo Perunovic (Psychology) – for a three-year term expiring December 31, 2021

This spring marked the end of the service terms for a number of REB members, including Dr. Erin Fredericks and Dr. Claire Goggin, both of whom concluded a three-year term on June 30, 2018. In addition, Dr. Sharon Murray's term also ended on June 30, 2018, following more than ten cumulative years of REB service. Dr. Murray made considerable contributions to the REB's deliberations and also engaged in professional development, attending both regional and national ethics conferences.

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.

Scope of REB Review

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 must have ethical approval from the REB prior to commencement. In the case of undergraduate research that does not pose more than minimum risk to participants, ethics approval may be granted by a research ethics committee at the departmental or program level, as per Section 2.7 of the REB Senate Policy (2016).

Planned amendments to the TCPS2 have resulted in a number of Canadian university REBs implementing an *exemption* from REB review for student course-based research activities that are conducted solely as a teaching exercise (Panel on Research Ethics, October 2016 at: http://www.pre.ethics.gc.ca/pdf/eng/tcps2-2016/Proposed_Revision_EN.pdf). The STU REB also began to implement this exemption during the 2017-2018 year.

Activities of the REB: July 1, 2017 – June 30, 2018

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, the REB **reviewed and approved 10 files, which is noticeably less than the number of files processed in previous years**. 2 applications were deemed to not require ethical review. Researchers reported **21 studies concluded** and had their files closed and **35 files were renewed** for another year. **2 adverse events were reported** (one remains under current investigation and the other has concluded).

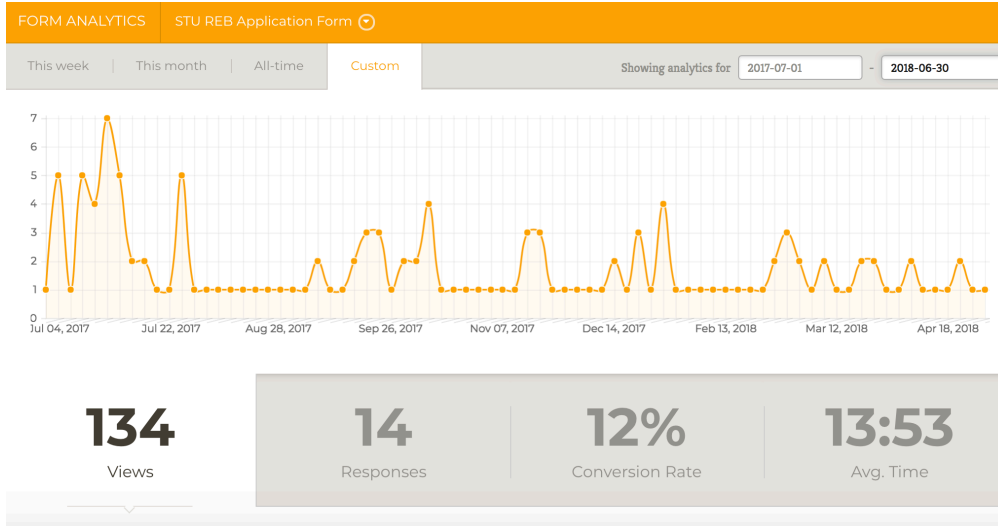


Diagram: STU REB Application Form Online Activity Report

The REB had **62 active research files** as of June 30, which includes the administrative work of renewing and closing existing files, as well as ongoing consultation with researchers involved in existing projects.

2) The TCPS2 (2014): Professional Development

As this document guides all activities, policies, and procedures of the REB, a number of measures are taken each year to ensure familiarity and compliance with the Policy Statement. These include:

CORE Tutorial Certification

Given how essential it is that all REB members become intimately familiar with the Tri-Council Policy Statement, all members of the STU REB are required to complete the TCPS2 CORE (Course on Research Ethics) tutorial and submit completion certificates to the Office of Research Services.

In addition, a number of faculty members opted to include the CORE tutorial completion as part of their departmental Honours program and senior seminar requirements. This reflects the increased awareness of research ethics among the STU community – a marker of success for the REB’s continual educational efforts.

Senate Research Ethics Board Policy Update – Ongoing Implementation Measures

Following the June, 2016 amendments to the Senate Research Ethics Board Policy, all applications for ethics approval of studies deemed to be above minimal risk must be accompanied by a CORE completion certificate. Efforts were made over the course of the year to publicize these changes (see below under “Educational Outreach Activities”) and to encourage compliance. Additionally, the June 2016 changes to the REB Senate policy also require the closure of all REB files that have been active for five years or more. This year, **2 researchers** were contacted and asked to reapply with updated documentation.

Professional Development

The REB Coordinator has finished her studies in a 2-year certification course offered through the Canadian Association for Research Administrators and has been given the designation of “Certified Research Administrator” or CRA.

During the fall term, the REB solicited requests from faculty members about potential seminar topics that would be of the greatest relevance and interest to their research portfolios. Following submission of a number of requests, in February, 2018 the STU REB hosted a two-part educational session on research ethics and digital research with Prof. Katie Warfield of Kwantlen Polytechnic University’s Department of Journalism & Communication Studies and Director of KPU’s Visual Media Workshop. The all-day event featured a morning session that was directed towards faculty members and an afternoon workshop for REB members. NBCC’s REB was also invited to attend and sent several members. The STU REB office received very positive feedback about the session.

3) Educational Outreach Activities

One of the key responsibilities of the STU REB, as outlined in Article 1.1 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) in November, 2017 to discuss the role of the REB and its activities. Particular focus was placed on the scope and requirements of departmental ethics review committees, as well as the REB review requirements for student research, including experiential learning opportunities and field placements. These points were summarized on a handout which was distributed at the meeting and made available electronically to the Dean for further reference (see Appendix B).

The REB Chair also presented to the Administration & Management Committee (AMC) in January, 2018. Emphasis was placed on the TCPS-2 grounds for exemption from REB review (e.g. program evaluation and quality improvement activities) as well as the REB review requirements for student research, including experiential learning opportunities and field placements (see Appendix C). As a result of this session, the REB was able to facilitate the implementation of the CBIE International Student Survey (in collaboration with Carrie Monteith-Levesque and Garry Hansen) in compliance with the TCPS-2, as well as aid additional administrative units in vetting survey requests (e.g. MacLeans).

The REB Chair also delivered a number of invited presentations to departments and senior seminars during the 2017-2018 year, namely:

- PSYC 4996
- Social Work Department (Jan, 2018)
- SCWK 5223: Organizing for Action with Diverse Groups (May, 2018)
- PSYC 3943 Advanced Research (March, 2018 guest lecture by REB Coordinator)

A TCPS-2 interpretation document was released by the Panel on Research Ethics in Spring 2017 which exempts minimal risk student research activities that are conducted solely for pedagogical purposes from REB review. Various efforts were undertaken to raise awareness about this change, including the design and distribution of an educational poster, handouts, and presentations to a number of university departments.

4) Departmental Consultation

The Acting Journalism Chair, Dr. Patrick Malcolmson, consulted with the REB Chair in May, 2018 about best practices for the ethical review of journalism related applications, as well as the scope of REB review within the context of journalistic work. It was determined that the majority of activities undertaken by journalism students at STU (e.g. investigative interviewing) would not fall within the TCPS2's definition of "research" and thus would not be subject to REB review. Instead, the ethical concerns of these activities are addressed under professional codes of ethics (e.g. Canadian Association of Journalists Principles for Ethical Journalism).

Plans for REB in 2018-2019

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. As of July 1, 2018, the position of REB Chair will be vacant. This will present serious issues for the ongoing management of active files and ethical review of incoming applications. **It is strongly recommended that greater recruitment efforts for the REB Chair be undertaken to ensure the position is filled prior to Fall 2018.**

2) TCPS2 (2014) Compliance

As part of the REB's annual efforts to ensure compliance with the TCPS2 (2014), a number of review and revision processes are planned for the 2018-2019 year. These include the ongoing development and maintenance of the REB website and online application form. Best practices continue to be recorded and developed alongside research ethics resources. Ongoing efforts to ensure St. Thomas University's compliance with the TCPS2 (2014) and its conformity to national research ethics practices and procedures **requires the appointment of a new REB Chair immediately.**

3) Educational Activities & Professional Development

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

Preparation of Interpretation Documents

In response to a number of frequently asked questions from STU researchers, the REB will continue its efforts to provide online resources for some of the more common terms and questions found concerning the TCPS2 (2014). Resources are posted on the ethics section of the STU website.

Presentation at 2018-2019 Chairs & Directors and AMC Meetings

It has been regular practice for the past four years for the REB Chair to present to the Departmental Chairs & Directors at one of their monthly meetings (preferably in the Fall

term), as well as the administrative teams at an AMC meeting. Given the current REB Chair vacancy, it is not known if these activities will continue. **It is strongly recommended that ongoing efforts are made to continue REB education at the upper administrative and faculty levels.**

Winter REB and STU Researcher Training Workshop

It has also been a regular practice over the past few years for the REB to organize educational seminars and workshops for the STU community. Given the current REB Chair vacancy, it is not known if these activities will continue. **It is strongly recommended that ongoing efforts are made to maintain the existing research ethics awareness at the institution.**

CAREB and CARA Conferences Attendance

In keeping with past practice, participation at both the regional and national research ethics conferences will be encouraged for the REB Chair, REB Coordinator, and all REB members (funds permitting).

Modernization and Documentation of REB Processes

Work is continuing with Josh Leslie of Stewardly, to streamline the processing and review of submissions. Work with Stewardly has formalized a one-year pilot program for multi-jurisdictional research review to be led by STU, and includes Cape Breton University REB, Health PEI REB, Mount Saint Vincent University REB, and the REB at NBCC (to reduce administrative burden and streamline review of low-risk studies looking to recruit on more than one Atlantic Canadian campus). The pilot will be launched in September and promoted (in order to expand and include more REBs) during Research Atlantic (formerly “CARA East”) in December at MSVU.

4) REB Administration

Following submission of a request to the Academic Vice-President for a course release as outlined in Article 17 of full-time Faculty Collective Agreement, the REB Chair was awarded a 3-credit hour course release for the 2017-2018 year. This year marked the end of Dr. Karla O’Regan’s term as REB Chair. Efforts to recruit a new chair from both current and former REB members began in September, 2017. Some initial interest was expressed from members of this group; however, when it was learned that the 3 credit-hour course release would not be offered for the position during the 2018-2019 year, this interest dwindled. A wider call for expressions of interest was sent from the Academic Vice-President’s office in April, 2018. To date, no applications have been received. **It is the strong recommendation of the REB that the position be re-advertised *with notice of a course release.***

St. Thomas University
Research Ethics Board Policy
Approved by Senate June 2005
Last Revised 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 research-attributable 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 REB
- 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.

THE REB @ STU

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 or with STU students (e.g. Honours projects)

Research conducted by students (that falls below minimal risk) should be conducted at **the departmental level.**

STUDENT RESEARCH

Department
Level
Review

Always below minimal risk

that is above
minimal risk

that is part of an
honours project

BUT also part of a
faculty member's
research activities

REB
Review

All risk levels

EXEMPT from REB review:

Student research that is both

- below minimal risk; and
- solely part of a teaching exercise

REB EXEMPTIONS

The TCPS2 provides grounds of review exemption for:

- research that is solely based on **publicly available information** (Article 2.2)
- **non-interventional observation in public places** (Article 2.3)
- exclusively **secondary use of data** (Article 2.4);
- quality assurance and **quality improvement studies, program evaluation** activities, and performance reviews, or **testing within normal educational requirements when used exclusively for assessment** (Article 2.5);
- **creative practice activities** (Article 2.6) unless done with an intention to obtain responses from participants

ARTICLE 2.5

Includes:

- staff performance reviews
- program assessments
- student course evaluations
- data collection for internal or external organizational reports
- course-based research activities intended solely for pedagogical purposes

If data are collected for the purposes of such activities but later proposed for research purposes, it would be considered secondary use of data not originally intended for research, and at that time may require REB review (see Ch. 5, TCPS2).



WHAT IS MINIMAL RISK?

“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**.”



THE REB @ STU

Researchers seeking REB review should:

- complete the TCPS2 [CORE Tutorial](#) and examine the [REB FAQs](#)
- complete an (online) [REB APPLICATION](#)
- **TIMING:**
 - REB meets once every month (except December, June, and July)
 - Applications should be submitted 2 weeks before the next available [meeting date](#)
 - Researchers can expect to hear back within 2 weeks of the file's review
 - Depending on what revisions or clarifications are needed, ethics approval can take **8-10 weeks**
 - **Delegated review** can be requested if the research is below minimal risk.
 - Review is conducted within a 2 week period by REB Chair + 2 other members

Consulting with the REB (or REC) Chair can help expedite the file review process.



ADMINISTRATIVE MATTERS

Highlights from STU REB Senate Policy:

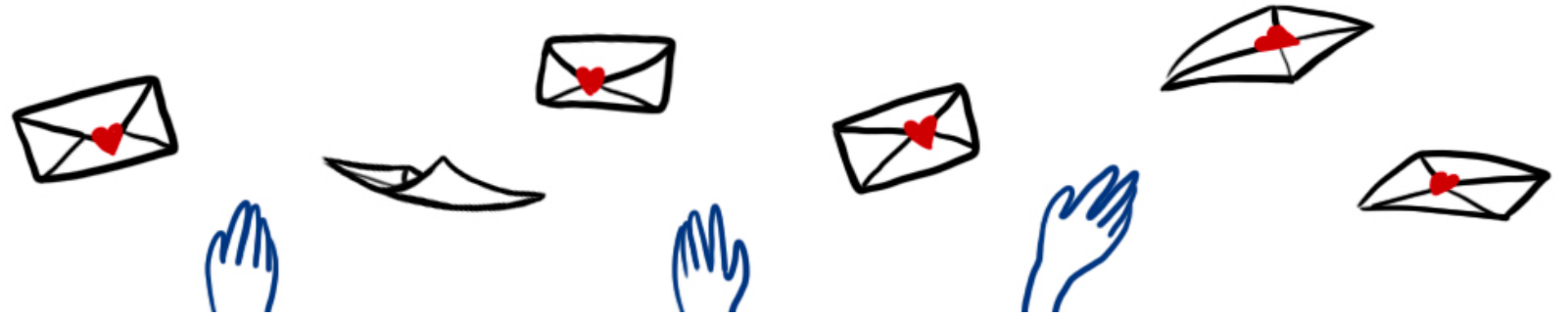
- REB Certificate period limited to 5 years
- [CORE completion certificate](#) **required for research above minimal risk**

Online REB Application Form allows you to share draft REB applications with co-investigators!

Many forms and [resources](#) are available from the REB website, including:

- [Amendment Request Form](#)
- [Unanticipated Issues Report](#)
- [Annual Report & Renewal Form](#)

QUESTIONS?



We'd love to hear from you!

Chair of the Research Ethics Board
To Be Announced (rebchair@stu.ca)

REB Coordinator
Danielle Connell (452-0621 or reb@stu.ca)

Summer/Fall 2018

Office of
**Research
Services**



St. Thomas
UNIVERSITY

Research Ethics Board

THE REB @ STU

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
 - includes use of STU list-servs & e-mail addresses (e.g. survey recruitment)
- by or with STU students (e.g. Honours projects, **field placements**)

Research conducted by students (that falls below minimal risk) should be conducted at **the departmental level.**



WHAT IS "RESEARCH" UNDER THE TCPS-2?

- Defined as a "a systematic investigation to establish facts, principles or generalizable knowledge."
- Must involve living humans as the *subject* of the research
- Determined on a case-by-case approach focusing on the nature and purpose of the proposed activities.

KEY CONSIDERATIONS

- What is the primary intent and objective(s) of the proposed activity?
(e.g. *generalizable knowledge* OR *organizational performance assessment*)
- How will the collected data be treated? (e.g. form of analysis, future use)
- Does the proposed activity form part of a faculty member's own research program or activities?

REB EXEMPTIONS

The TCPS2 provides grounds of review exemption for:

- research that is solely based on **publicly available information** (Article 2.2)
- **non-interventional observation in public places** (Article 2.3)
- exclusively **secondary use of anonymous data** (Article 2.4);
 - no possibility of data linkage or generation of identifiable information
- quality assurance and **quality improvement studies, program evaluation** activities, and performance reviews, or **testing within normal educational requirements when used exclusively for assessment** (Article 2.5);
- **creative practice activities** (Article 2.6) unless done with an intention to obtain responses from participants

January, 2018

ARTICLE 2.5

Includes:

- staff performance reviews
- **program assessments**
- student course evaluations
- data collection for internal or external organizational reports
- **course-based research activities intended solely for pedagogical purposes**

If data are collected for the purposes of such activities but later proposed for research purposes, it would be considered secondary use of data not originally intended for research, and at that time may require REB review (see Ch. 5, TCPS2).



January, 2018

ETHICAL PRACTICE OUTSIDE THE TCPS-2

Activities which fall outside the scope of REB review “may still raise ethical issues that would benefit from careful consideration by an individual or a body capable of providing some independent guidance, other than an REB. These ethics resources may be based in professional or **disciplinary associations**, particularly where those associations have established best practices guidelines for such activities in their discipline” (TCPS-2, Article 2.4 Application).

January, 2018

Office of
Research
Services



St. Thomas
UNIVERSITY

Research Ethics Board

RESEARCH ETHICS GUIDELINES

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans created in 1998 by:

- Canadian Institutes of Health Research
- Natural Sciences and Engineering Research Council
- Social Sciences and Humanities Research Council

Updates:

December 2010: 2nd edition released

December 2014: [TCPS 2 \(2014\)](#) released

[Proposed Amendments](#) (2018)



January, 2018

FROM THE VIEW OF PARTICIPANTS



What is the research study about?

- What is the researcher trying to understand in the research study?
- Why did the researcher invite me to take part in the research study?

What will I be asked to do?

- What steps will I be asked to follow?
- What tests or medications will I be asked to take?
- What information will be collected from me?
- How much time will the study take?

What will happen to my information?

- Who gets my information and who uses it?
- How will my information be protected?
- How long will my information be kept?
- Can I change my mind about how or whether my information will be used?

What are the risks?

Some research studies have little risk. Others have higher risks. Some risks are unknown.

- What kinds of risks are possible (for example physical, emotional, social)?
- Are the risks common or are they rare?
- Will the risks have small or major consequences for me?
- How will the risks be managed?
- How might the risks impact me in my life?

What are the possible benefits?

Some research studies may benefit participants directly. Others do not offer any direct benefits, but the results may help others, or add to existing knowledge or practices.

- Do the possible benefits matter to me?
- Do I want to help improve existing knowledge or practices?

REB REVIEW & EXPERIENTIAL LEARNING

Whether REB review is needed for field or community-based activities depends on the **nature of the work being done**.

- NO class or categorical exemptions
- Each case determined on its own circumstances
- **Key considerations:**
 - What is the nature of the activity the student(s) will be conducting?
 - Will the placement or experiential activity generate findings? If so, how will they be used? What is their intended purpose? (e.g. internal assessment vs. generalizable knowledge)
 - Will the student work/findings be used for any additional purposes (e.g. faculty research)
 - Does one of the TCPS-2 exemptions apply?

Student Research & Research Ethics

What is "minimal risk"?

The Tri-Council Policy Statement on Research Ethics (TCPS-2) defines minimal risk within the context of each research study and the everyday lives of its participants. If participants face no more risk of harm by participating in a study than they might normally encounter in the course of their daily lives, it is minimal risk research.

Department Level Review

Departments report these reviews annually to the REB

Student research with human participants that is:

more than minimal risk

part of a faculty member's research program

part of an Honours or Directed Research project

only a teaching exercise or a program evaluation

REB Review

EXEMPT from review per Article 2.5 TCPS-2 (2014)

WHAT IS MINIMAL RISK?

"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**.

DEPARTMENTAL LEVEL REVIEW

- Research must be below minimal risk
- Reviews must adhere to the TCPS-2
- Results of these department-level reviews must be reported to the REB on an annual basis
- Ideally composed of 3 full-time members
 - cannot be a supervisor of the research
 - better when the Department Chair or Program Director is not involved
 - can include members who are external to the Department, when needed
- A letter outlining the outcome of the review and its reasons should be sent to the applicant.
 - Help out and cc: the REB!

January 2018

THE REB @ STU



St. Thomas University

Researchers seeking REB review should:

- complete the TCPS2 [CORE Tutorial](#) and examine the [REB FAQs](#)
- complete an (online) REB APPLICATION
- **TIMING:**
 - REB meets the **third week** of every month (except December, June, and July)
 - Applications should be submitted 2 weeks before the next available meeting date
 - Researchers can expect to hear back within 2 weeks of the file's review
 - Depending on what revisions or clarifications are needed, ethics approval can take **8-10 weeks**
 - **Delegated review** can be requested if the research is below minimal risk.
 - Review is conducted within a 2 week period by REB Chair + 2 other members
 - Offered at the discretion of the Chair

Consulting with the REB office can help to identify issues early on and expedite the file's review.

January 2018

WHAT'S NEW?

Important revisions to REB Senate Policy:

- REB Approval period limited to 5 years
- CORE completion certificate now **required for research above minimal risk**

New **online** REB Application Form!

Online [REB Registration](#) allows you to share REB applications with co-investigators.

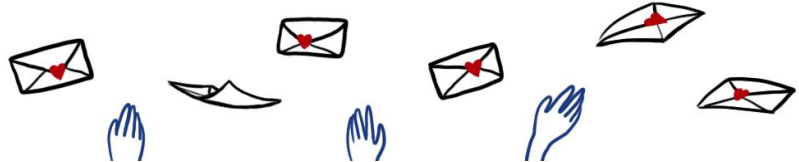
Many other forms now available for online submission from the [REB website](#):

- Sample Confidentiality Agreements, Consent Forms
- Annual Report & Renewal Requests

January 2018



QUESTIONS?



We'd love to hear from you!

Chair of the Research Ethics Board

Dr. Karla O'Regan (460-0437 or rebchair@stu.ca)

REB Coordinator

Danielle Connell (452-0647 or reb@stu.ca).

January 2018

