

St. Thomas University
Research Ethics Board
Annual Report 2014-2015

Prepared by
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Chair, Research Ethics Board

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Research Ethics Board Annual Report 2014-2015

Consistent with the responsibility requirements established in the Research Ethics Board Policy (approved by Senate, 2011), this report summarizes the responsibilities and activities of the REB from July 01, 2014 to June 30, 2015.

The records of the REB indicate that no annual report was filed for the 2013-2014 year on account of the Chair position having been vacant and/or filled in only an acting capacity. This position was filled on July 1, 2014 for a three-year term.

Responsibilities of the Research Ethics Board

(Article 1.1, St. Thomas University Research Ethics Board Policy)

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 and experimental teaching protocols;
- 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 of STU;
- enhancing the research ethics education of the STU community
- preparing an annual report for submission to the President;

- developing and participating in continuing and professional education relating to ethics and the use of human participants

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, 2014-2015

Member	Representation	Expiration of Appointment
Chair: Karla O'Regan	Criminology	June 30, 2017
Brian Carty	Social Work	April 30, 2017
Matthew Hayes <i>on sabbatical</i>	Sociology	February 28, 2015
David Korotkov <i>on sabbatical</i>	Psychology	August 31, 2016
Sue McKenzie-Mohr	Social Work	August 31, 2016
Sharon Murray	Education	June 30, 2016
Alanna Palmer	Community	Sept 30, 2017
Josephine Savarese	Legal	Sept 30, 2017
Nicholas Sehl	Community (alternate)	Sept 30, 2017
Ray Williams	Education	April 30, 2017

New Members as of September, 2015: *(pending appointment approval)*

Claire Goggin (Criminology) – for three year term expiring August 30, 2018
 Erin Fredericks (Sociology) – for three year term expiring August 30, 2018

The Board is also actively seeking membership from the Humanities.

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 2014-2015

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 18 files**. Also, 17 studies concluded and had their files closed with only 1 adverse event reported (which was mitigated immediately by the researcher) and 35 files were renewed for another year.

The REB has **57 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 the President (March 26, 2015) for a jurisdictional review of a student-based project in journalism for the purpose of determining whether the project fell within the definition of “research” under the TCPS2. A response to this request was filed with the Office of the Vice-President (Academic & Research) on March 30, 2015.

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

A new Tri-Council Policy Statement on the Ethical Conduct for Research Involving Humans was released in December of 2014. As this document guides all activities, policies, and procedures of the REB, a number of measures have been taken to ensure familiarity and compliance with the new Policy Statement. These include:

a) *CORE Tutorial Certification*

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 are required to complete the TCPS2 CORE (Course on Research Ethics) tutorial and submit completion certificates to the Office of Research Services. Although a revised CORE tutorial has not yet been released for the new version of the TCPS2 (2014), all REB members will renew their completion certificates if/when a new tutorial becomes available.

b) *Senate Research Ethics Board Policy Update*

The REB underwent 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 will be submitted to Senate for approval at the September, 2015 meeting.

c) *Professional Development*

The REB Chair and Coordinator each attended separate educational workshops related to the revised (2014) version of the TCPS2 at the Canadian Association of Research Ethics Boards (Vancouver, May 2015) and Canadian Association of University Research Administrators (Halifax, November 2014), respectively. This learning was shared with the full REB, including a review of the Interagency Advisory Panel on Research Ethics (PRE)'s *TCPS2 (2014) Companion Document*, which highlights the significant areas of revision between the 2010 and 2014 versions of the Policy.

A number of REB members (including both the Chair and the Coordinator) also attended a seminar offered by UNB's Centre for Enhanced Teaching & Learning that focused on the ethical issues raised within SoTL (Scholarship on Teaching and Learning) research, i.e. doing research with student participants. The seminar was offered on May 17, 2015 by Dr. Pierre Boulos (University of Windsor).

The REB Coordinator has enrolled in a 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 begin in September 2015.

3) **Ethics Education: CAREB and CARA Conferences Attendance**

The REB Coordinator attended the 2014 Canadian Association of Research Administrators (CARA) Conference in Halifax in November, 2014. The REB Chair attended the annual meeting of the *Canadian Association of Research Ethics Boards (CAREB)* in Vancouver in May, 2015. These events provide sessions on research ethics related issues both nationally and internationally, with an aim for practical application

through the use of case studies and issue-based discussion. Participation in these events provides immeasurable assistance to the REB both in its review practices and its awareness of current issues and applied solutions.

4) Educational Outreach to STU Community

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, 2014 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 also hosted an educational seminar on research ethics and social media research. Dr. Gordon DuVal, Chair of the National Research Council's REB, delivered a seminar entitled, "Researching Online: Facebook and Beyond" at St. Thomas University on March 12, 2015. It was well attended and received very positive feedback from faculty.

Plans for REB in 2015-2016

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" is being 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 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 efforts to ensure compliance with the new TCPS2 (2014), a number of review and revision processes are planned for the 2015-2016 year. These include amendments to the REB Senate Policy document, the REB application form, and the REB's Standard Operating Protocols (SOPs). In addition to adhering to the new TCPS2 (2014) requirements, this review process should also increase St. Thomas University's 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, 2015 Chairs Meeting

Continuing with the practice established this past year, 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 TCPS2 (2014) will be discussed in conjunction with distribution of the PRE's *Companion Document to the TCPS2 (2014)*. All materials will also be made available on the STU REB website.

b) Preparation of Interpretation Documents

In response to a number of frequently asked questions from STU researchers, the REB plans to provide “interpretation documents” for some of the more common terms and standards found within the TCPS2 (2014). Possible topics include: the definition of “research” under the TCPS2; the meaning of “minimal risk”; standards of data security; the limits of departmental review; etc... These documents will be made available on the REB website.

c) Collaborative Ethics Policy with Journalism

In response to queries from both faculty researchers and administrators, the REB plans to collaborate with the Office of Research Services and the Department of Journalism to establish a university policy on how research ethics compliance can be best ensured with journalistic research.

d) CAREB and CARA Conferences Attendance

As in past years, participation at both the CAREB and CARA 2015/2016 conferences will be encouraged among all REB members (funds permitting)

e) Regional Hosting

Discussions are underway to plan one day CAREB New Brunswick event, possibly hosted by either UNB & STU or Mount Allison University. Initially, a CAREB Atlantic event was not going to take place due to the lack of interest in hosting, but at CARA National in Toronto last month it was decided to pursue this further by pooling our collective resources.

4) REB Administration

To facilitate a more equitable and efficient file review process, the REB will 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.

In addition, a “reviewer rotation” schedule will be established at the Board level so as to increase the efficiency of delegated reviews and ensure a more balanced workload among file reviewers.

Research Ethics Board Policy

Approved by Senate, June 2005

Revised and approved by Senate, June 2011

Preamble

St. Thomas University endorses the principles set out in the “**Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans**” (current version) and this document describes how STU will apply Tri-Council policy. The issues below are worded using the language employed in the TCPS (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 principles of respect for 1) persons, 2) concern for welfare, and 3) justice.

Review is available normally only to members of the STU research community, researchers in formal collaboration with STU members, or for research conducted at STU by outsiders (UNBF researchers see Appendix A). For the purposes of this policy, the term "STU research" will be used to refer to all three categories of research. The term "Research" is understood as an undertaking intended to extend knowledge through a disciplined inquiry, or systematic investigation but not including quality assurance studies, quality improvement studies, program evaluation activities, performance reviews, creative practice activities, or testing within the normal educational requirements. Researchers who are unsure if their project is considered “research” please contact the REB Chair.

This policy requires that all research projects involving human participants undertaken by members of the university community -- including all faculty, staff and students, including students carrying out research as part of class assignments -- fall within the jurisdiction of the STU Research Ethics Board, irrespective of the source of financial support (if any) and irrespective of the location of the project, in the latter case so long as the investigator represents the work as STU research. 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.

1.0 Terms of Reference

1.1 Responsibilities

St. Thomas University Research Ethics Board (REB) is responsible to the President through the Assistant 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 of STU;
- preparing an annual report for submission to the President;
- participating in continuing education organized by STU research administrators for the University community in matters relating to ethics and the use of human participants

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).

1.2 Composition of REB

The REB shall be made up of no less than 5 members, including both men and women, and 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 should be capable of alerting the REB to legal issues and implications in relevant areas of research.
- Substitute members may be appointed at the discretion of the President. Substitute members can be called in to replace 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 who shall seek advice from the Senate prior to making appointments to the Board.

The REB will have access to a legal expert (other than the University's legal counsel) knowledgeable in the applicable law.

The President shall appoint one member of the REB to serve as Chair for a maximum term of three years.

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.

1.3 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.

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

1.4 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.

The STU REB will have jurisdiction over all research involving human participants. All STU research involving human participants will proceed after ethical approval has been granted by the REB or in the case of undergraduate research, the appropriate departmental Research Ethics Committee.

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 the Preamble) 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.

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. Researchers who are unsure if their project is considered "research" are to contact the REB Chair.

2.2 Ethics Review

The effective working of ethics review -- across the range of disciplines conducting research involving human participants -- requires a reasonable flexibility in the implementation of common principles. This policy, therefore, seeks to express the shared principles and wisdom of researchers in diverse fields.

Research involving humans, including biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells must be reviewed by the REB. Review by the REB is also necessary for such materials taken in routine situations but which are later used for educational purposes.

All 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

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: it does not involve any intervention staged by the researcher, or direct interaction with individual(s); individuals have no reasonable expectation of privacy and; dissemination of research findings will not allow identification of individuals

c) research that relies exclusively on secondary use of anonymous data

d) quality assurance studies, quality improvement studies, program evaluation activities, performance reviews, creative practice activities and testing within the normal educational requirements.

2.3 Scholarly Review

a) In case of research proposals that present more than minimal risk (see page 23), 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. 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, at most, 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 based on the general principle that the level of scrutiny of a research project is determined by the level of risk it poses to the participants.

2.5 Normal Review Process

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

In case of controversial research proposals, the REB may meet face to face with researchers 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. Minutes will be kept for these meetings by the Office of the Assistant Vice-President (Research) and inserted into the appropriate case files.

The REB shall keep an "open file" in a secure place in the Office of the Assistant Vice-President (Research) 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 Office of the Assistant Vice-President (Research) and the STU REB, these files shall be "closed" and kept as records demonstrating compliance with the Tri-Council Policy. The files remain the property of STU and cannot be removed from the Office of the Assistant Vice-

President (Research) 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, as well as that receiving departmental level review 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 face-to-face meetings of the REB members. It is usually 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 an appropriate time. 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 review by the Chair of the REB and two members rather than the full REB. It is available only in cases which fulfill one of the following criteria:

a) The research obviously involves no more than minimal risk (as defined in the Tri-Council Policy Statement, page 23: "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"). The researcher is responsible for an acknowledgement of minimal risk to the REB.

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 approved research

d) annual renewals of more than minimal risk research where there is no further data collection involved but data analysis is ongoing.

2.7 Departmental Level Review

This policy requires that all Faculty research must be submitted to the REB (see section

1.4). If however a study is a teaching exercise (i.e., part of an undergraduate course and/or Honour's project), and entailing no more than minimal risk, it must 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.

Student research deemed to be beyond minimal risk must 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 is required.

d) The REB shall be promptly notified by the researcher when the project concludes by completing the "Annual/Final Report on Research Involving Humans" Form.

2.9 REB Conflict of Interest

If an REB is reviewing research in which a member of the REB has a personal interest in the research under review (e.g., as a researcher or as an entrepreneur), conflict of interest principles require that the member 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 other members of the REB should make a final decision regarding how to proceed.

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 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 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 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) the Assistant Vice-President (Research), and will be available to the President and Vice-President Academic through the office of Research.

Any decisions by the Chair to approve minor amendments without full committee review will be reported to the REB and recorded in the minutes.

An annual activity report from the REB will be made to the President through the Office of the Assistant 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 (TCPS), and in accordance with the principle of proportionate review from the TCPS, the following alternative review models avoid “unnecessary duplication of review without compromising the protection of participants” (TCPS2, article 8.1, pg., 99).

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 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.

*To determine if a study is minimal risk, the researcher must provide the STU REB Chair with all relevant information to make that determination.

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 Assistant 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
- advising their faculty members about the need to comply with the Tri-Council Policy statement.

Individual departments are 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. 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.

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.

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 through the Assistant Vice-President (Research) any cases which undermine STU's compliance with the Tri-Council Policy and the President shall decide if and/or what sanctions or penalties to impose on the researcher(s).

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.

Appendix B – Chairs meeting hand-out

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 falls below minimal risk 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

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. Great for Honours students!

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

Multi-Jurisdictional Review:

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:

- The study will not be conducted at STU
- The study is considered minimal risk
- The STU researcher is not the principal investigator
- 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, which adheres to the TCPS2

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 (section 2.2)

Observation in public places (section 2.3)

Secondary use of data or biological materials (section 2.4)

These exemptions apply to:

- Research based on existing information in the public domain (e.g. news articles, Statistics Canada surveys). However, 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:
 - any staged interventions or direct interactions with those being observed;
 - reasonable expectations of privacy on the part of those observed;
 - 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. However, if the data are later used for research purposes, that project would 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:
 - the data or samples are anonymous; and
 - there is no way the data can be linked to the individuals who provided it;
 - and not follow-up contact with the original study's participants occurs

The REB as Resource

The Board exists as part of an institutional acknowledgement of research as an essential component of the University's mission. It functions as a researcher's resource, not a policing body. Its goal is to foster research, aid researchers as they prepare for fieldwork or study conditions, provide assistance when problems or issues arise during a project, and facilitate ethics education among University members.

- Don't know if your project requires ethical review?
- Not sure if your study falls within the parameters for ethical review exemption or multi-jurisdictional review?
- Wondering if a student's thesis work falls below minimal risk?
- Have a good idea for a Research Ethics workshop or educational event?

Just ask!

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REB Members:

Brian Carty, (Social Work)
Danielle Connell, Administrative Assistant
Matthew Hayes, (Sociology)
Dave Korotkov, (Psychology)
Sue McKenzie-Mohr (Social Work)
Sharon Murray, (Education)
Karla O'Regan, Chair (Criminology)
Alanna Palmer, Community Member
Nicholas Sehl, Community Member (alternate)
Ray Williams, (Education)