

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

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

Research Ethics Board Members, 2015-2016

Member	Representation	Expiration of Appointment
Chair:		

General information

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

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

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

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

Activities of the REB in 2015-2016

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

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

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

In addition, the REB responded to a request by Dr. Catherine Gidney (October 18, 2015) for a review of her project funded by the Nova Scotia Health Research Foundation for the purpose of determining whether the project fell within one of the TCPS2's grounds for exemption from REB review (Articles 2.2 and 2.4). The project was found to fall within these Articles and thus deemed exempt from REB review. A letter outlining this decision was sent to the researcher and filed with the Office of Research Services. All research must be approved by 8(h)63(i)91(s)1.

a) *CORE Tutorial Certification (ongoing)*

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

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

b) *Senate Research Ethics Board Policy Update*

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

c) *Professional Development*

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

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

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

2) TCPS2 (2014) Compliance

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

3) Educational Activities & Professional Development

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

a) Presentation at the Fall, 2016 Chairs Meeting

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

b) Presentation at the Spring 2017 AMC Meeting

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

c) Requested in-class Presentations, 2016-2017

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

Research Ethics Board Policy

Approved by Senate, June 2005

Revised and approved by Senate, June 2016

Preamble

St. Thomas University endorses the principles set out in the “**Tri**

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

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:

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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(t28(o)-62(e)7(n)63(s)14(u)63(r)21(e))

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

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

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-

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

6.2 University Support

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

6.3 Sanctions

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

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

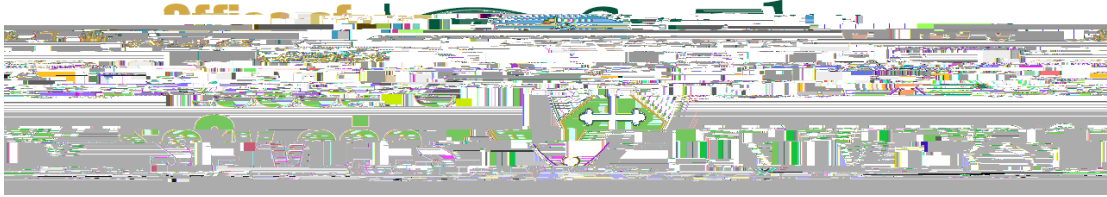
Appendix A

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

REB Policy Companion Document
Executive Summary of Revisions

June 14, 2016

Aside from HGLWRULDO FKDQJHV 3H 5HVSRQVLRKLDW@OLHX RI †HDO



Research Ethics Board
Presentation to Chairs



Research Ethics Board
reb@stu.ca

F RECENTLY ASKED QUESTIONS

8. How are applications processed?

During the teaching terms, reviews are normally conducted by the full board during monthly meetings. During holiday seasons, reviews of projects deemed by the REB to be of minimal risk (see FAQ #0) typically undergo delegated review (sub-committee) rather than full board review.

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

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

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

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, if the research can be said to be of minimal risk, the research can be said to be of minimal risk.

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

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

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

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

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

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

If you are in a multi-jurisdictional review, you must provide documentation showing that the study has been approved by the REB of the principal institution. This documentation must be submitted to the STU REB.

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

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



Research Ethics Board

AMC Presentation, April 28th, 2016

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involving human participants that is conducted:

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

D E B (RECs):

- x 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 of the project (who h

risk

- x report annually (in May) to the REB on review processes and outcomes conducted throughout the year
- x may consult with the REB Chair on difficult or more complex issues

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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, Z K H U H D S H U V R Q | V S D U W L F b S D W L R Q L Q W K H
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Ultimately, the decision on the level of risk rests with the Board, and you should do your best to DV V H V V \ R X U S U R M H F W | V G H J and communicate the basis for this assessment in your application. After all, member of the REB will know your research better than you, so thinking through the risks of experiences you anticipate your participants will have will help to determine the risks the research raises. No matter what the level of risk, focus your application for approval on making it clear to the Board how you are ensuring the TCPS2 ethics requirements are being met in your project.

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

- 2. 2)
- 2. 3)
- 2. 4)
- 2. 5)

These exemptions apply to:

- x 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 that are not already public knowledge, the exemption may not apply.
- x Observational research that studies human behaviour under natural circumstances (e.g. shoppers in a mall, hockey fans in an arena, discussants in an online forum). The observational research must not involve:
 - o any staged interventions or direct interactions with those being observed
 - o reasonable expectations of privacy on the part of those observed;
 - o the identification of specific individuals in any disseminated results
- x (e.g. quality assurance, performance reviews) or testing within normal educational requirements used exclusively for assessment, management or improvement purposes, if the data are later used for research purposes or wide dissemination of results, the project may require REB review
- x (e.g. school records, online opinion sites, . Data files or samples from one study may be useful for other research purposes on their own or when FRPELQHG ZLWK LQIRUPDWLRQ IURP DQRWKHU VWXG\ 7 require REB review as long as:
 - o the data or samples are anonymous and
 - o there is no way the data can be linked to the individuals who provided it;
 - o and not follow XS FRQWDFW ZLWK WKH RULJLQDO VWX

CORE16

Provides an applied approach to the TCPS2, an 8-module, self-paced course featuring interactive exercises and multi-disciplinary examples, many of which employ current or well known events that trigger ethical issues. Comes with a certificate of completion.

[http://web.cgsa.ca/eth](#)

