

St. Thomas University
Research Ethics Board Policy
Approved by Senate June 2005
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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.