

RESEARCH REQUIRING ETHICS REVIEW

Section:	Academic/Student (AC)
Subject:	Applied Research
Legislation:	
Effective:	January 21, 2005
Revision:	January 29, 2013; September 1, 2016 (reformatted); December 13, 2016

APPROVED: _____
President and CEO

POLICY

The policy of the Board of Governors is to establish principles that promote and facilitate the conduct of all research in ways that respect human dignity and that demonstrate concern for the welfare of living human research participants, in accordance with national human research ethics policies.

PROCEDURE

DEFINITIONS

Chair For the purpose of this procedure, a reference to the Chair of the Research Ethics Board includes a reference to the Co-Chairs of the Research Ethics Board (REB).

Delegated review A review by one or more members of the REB in place of the full REB, or by an instructor who has requested and been given permission from the REB to carry out the review in the REB’s place in a situation where the instructor has a student performing research that is part of the coursework and that poses no more than minimal risk to human participants.

Human biological material Human tissues, whether dead or alive, including but not limited to blood, urine, saliva, or other bodily fluids; tissues; hair or nails; placentas and umbilical cords; sperm, oocytes, and

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products of conception; excess pathology tissue and waste surgical tissue.

Human participant

A human, whether alive or not, who by virtue of involvement in a data-gathering situation or activity (for example, direct observation, questionnaire or interview), is a source of primary data or information.

Minimal risk

The probability and magnitude of possible harms that the research will cause to human participants is no greater than those that the human participants encounter in those aspects of their everyday life relating to the research.

Multi-centered research

Research that requires review by more than one research ethics board, such as is the case where research involves more than one post-secondary institution.

Principal investigator

The lead investigator completing the research.

Research

An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation to benefit human society.

Research Ethics Board (REB)

The SAIT board that reviews research applications to ensure that researchers comply with this procedure.

Research involving humans

Any research that involves human participants or human biological materials.

Researcher

Any member of the SAIT community or any person external to the SAIT community who conducts or carries out research using SAIT resources and/or formally using members of the SAIT community as human participants. This includes but is not limited to researchers carrying out scholarly activity, applied research, and/or research under the terms of a Cadmus Trades Teaching Chair award or a Cisco e-Learning Chair award.

SAIT community

All persons employed on SAIT's payroll (whether paid by annual salary or hourly wage), members of SAIT's Board of Governors, students, contractors, consultants, agents and volunteers.

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The Canadian Institutes of Health Research (CIHR), the Social Sciences and Humanities Research Council of Canada (SSHRC) and the Natural Sciences and Engineering Council (NSERC) jointly issued a revised national human research ethics policy in 2010, referred to as the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, or TCPS2.

GOVERNING PRINCIPLES

1. The wording and contents of this procedure have been adapted from and comply with the TCPS2, and, in particular, with that document's Core Principles and Articles. For the purposes of this procedure, TCPS2 refers to the most current official document of this nature, whether or not it is formally labelled as TCPS2.
2. Changes to the TCPS2's Ethical Principles and/or Articles are deemed to be a change to and revision of corresponding sections of SAIT's procedures, provided that those changes or revisions are approved through SAIT's policy/procedure approval process.
3. This procedure applies to all researchers, as defined by this procedure.
4. A researcher must simultaneously consider two obligations in the design and conduct of research: the obligation to conduct research as capably as the researcher's knowledge permits, and the obligation to protect and preserve the human participants' dignity and wellbeing. The TCPS2 is the minimum standard that a researcher must follow when working with human participants. In particular, a research must consider the TCPS2 Core Principles of:
 - a) Concern for Welfare;
 - b) Justice;
 - c) Respect for Persons.
5. A researcher is responsible for:
 - a) Being properly qualified and versed in the conduct of ethical research;
 - b) Monitoring the research to ensure that it is conducted in an ethical manner;

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- c) Reporting unanticipated issues or changes to the research; and
 - d) Supervising all team members in the application of the research procedures.
6. SAIT recognizes that the analysis, balance and distribution of harms and benefits are critical to the ethics of human research. This includes the importance of maximizing the benefit of research, while minimizing harm to human participants. The anticipated benefits of research must outweigh its foreseeable harms. Researchers have an obligation to reduce or eliminate potential risks so that they do not subject human participants to unnecessary risks of harm.
7. The REB will regularly report to the vice president, academic on its activities, including delegated reviews.

PROCEDURE

A. Status and Authority of the Research Ethics Board (REB)

1. This procedure establishes:
 - a) An independent REB separate from other research bodies at SAIT, with the institutional authority and mandate to review the ethical acceptability of research in compliance with TCPS2;
 - b) The principles and practices under which the REB makes its decisions.
2. SAIT will provide the REB and its members with:
 - a) The professional development opportunities needed for REB members to maintain their currency with the TCPS2 and to carry out their duties;
 - b) The support and resources necessary for REB members and the REB to carry out their duties, including its review duties and its continuing ethics review duties.
3. The REB's Terms of Reference are set out in Schedule A, an Associated Document to this procedure.
4. The REB may create processes by which the research that students carry out as part of their coursework may be reviewed by a constituted School/Department Review Committee. Please see Schedule B, an Associated Document to this procedure.

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B. Obtaining REB Approval

1. All researchers as defined by this procedure must, subject to the exceptions set out in paragraph B.2 of this procedure, submit their research applications to and have their research applications approved by the REB before starting their research.
2. Certain types of research activities do not require REB approval. These activities include:
 - a) Research that does not involve human participants as defined by this procedure.
 - b) Research about a human participant that is based on information contained in materials that are legally available and accessible to the public (for example, court records, archival records, news articles, etc.), provided that neither the human participant nor any third party is approached directly for interviews or for access to private materials.
 - c) Research involving the observation, assessment, and/or recording of public behavior in a public forum (for example, hockey fans in an arena, political rallies, demonstrations, public meetings, etc.), under natural circumstances, since it is expected that the human participants are seeking public visibility and therefore observation and possible recording.
 - d) Quality assurance studies, performance reviews of any organization, or its employees or students within the mandate of the organization, or testing within normal educational requirements, unless they contain an element of research in addition to assessment.
 - e) Procedures and practices exclusively used for pedagogic purposes (for example, classroom discussion, workplace experiential learning observation) without a research component. Such procedures and practices do require attention to other professional standards of ethical conduct.
 - f) Course-based research activities intended solely for pedagogical purposes and that pose minimal or no risk; approval of those activities may be delegated to applicable faculty and/or academic chairs.
3. A researcher shall obtain advice from the REB whenever there is any ambiguity or doubt as to whether the proposed research requires REB approval.
4. A researcher will submit the application using the format that the REB prescribes.

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5. The REB administrator will forward the application to the vice president, academic, for determination of whether the proposed research aligns with SAIT's strategic direction and/or priorities. The vice president, academic shall make this determination within five business days of receiving the application from the REB administrator. This step is not part of the REB approval process.
6. If the vice president, academic determines that the proposed research does not align with SAIT's strategic direction and/or priorities, the REB administrator will advise the researcher accordingly, and the application will not proceed to the REB.
7. If the vice president, academic determines that the proposed research aligns with SAIT's strategic direction and/or priorities, the REB administrator will forward the application to the REB Chair.
8. The REB Chair will review the application to determine the level of review required:
 - a) In the case of proposed research being carried out by a researcher who is not a student,
 - i) If the proposed research poses greater than minimal risk, the REB must conduct a full review of the application;
 - ii) If the proposed research poses no more than minimal risk, the Chair may delegate review of the application.
 - b) In the case of proposed research being carried out by a student as part of the student's coursework,
 - i) If the proposed research poses greater than minimal risk, the REB must conduct a full review of the application;
 - ii) If the proposed research poses no more than minimal risk, the student's instructor may request a delegated review and shall contact the REB for further information on this process. The Chair shall determine whether a delegated review is appropriate or whether the REB must conduct a full review of the application.
 - c) Where the REB conducts a full review of an application, it shall render its decision no more than 45 business days after receiving a properly-completed application. This time period may be extended during the summer: applications that the REB receives in July and August will not be reviewed until the REB's first meeting in September.

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- d) The REB may conduct a full review of an application in a face-to-face meeting, via teleconference or via e-mail.
9. The REB shall base its decisions on SAIT's policies and procedures and on the TCPS2 and other relevant external policies.
10. The Chair will discuss suggested changes to the application with the principal investigator(s). The principal investigator(s) will provide amendments to the REB. The REB may request a new application if there is a high level of risk and the application requires numerous changes.
11. If the REB approves an application, the Chair shall sign a Certificate of Ethics Approval, and the REB will issue this document to the principal investigator(s).
12. Before the REB makes a decision that would result in the denial of a researcher's application, the REB shall provide the researcher with its proposed reasons for doing so, and the researcher has the opportunity to reply before the REB makes that final decision.
13. If the REB denies an application or makes approval contingent on changes to the proposal, the REB shall provide the researcher with written grounds for that decision.
14. The REB's decision to approve an application is final.
15. A researcher has the right to request, and the REB has an obligation to provide, prompt reconsideration of the REB's decisions affecting a research project. A researcher and the REB should make every effort to resolve their disagreements through deliberation, consultation and/or advice.
16. If a disagreement cannot be resolved through reconsideration, or if the REB's decision is to deny an application, the researcher may appeal the REB's decision through the established appeal mechanism, as follows:
 - a) The REB's appeal mechanism is the University of Calgary's Research Ethics Appeal Board (REAB);
 - b) A request for appeal is the last resort and may be granted only on procedural grounds or when there is a significant disagreement over an interpretation of the TCPS2;
 - c) The REAB's decision is final and binding.

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C. Continuing Research Ethics Review

1. The REB makes the final determination as to the nature and frequency of continuing research ethics review in accordance with a proportionate approach to research ethics review. At a minimum, continuing research ethics review consists of an annual status report (for multi-year research projects) and an end-of-study report.
2. Research that involves no more than minimal risk to human participants should be held to the minimum requirements for continuing ethics review; that is, an annual status report. Consistent with a proportionate approach, the REB may request more frequent and/or more substantive reports, at its discretion.

D. Research Funding

1. A researcher is strongly encouraged to submit the research application to the REB for its review and approval prior to submitting the proposed research to a funding agency. If a funding agency approves a researcher's proposed research before the REB has reviewed and approved it, the REB shall review and make an independent decision on the ethics application without considering the implications that its decision has on the research funding.
2. A researcher may not begin the research until the REB has reviewed and approved the research application, regardless of whether or not the researcher has already obtained funding for the research.

E. Reports of Unanticipated Issues

1. A researcher shall immediately report to the REB any unanticipated issue or event that may increase the level of risk to human participants or that has other ethical implications that may affect the human participants' welfare.
2. The report to the REB should include a description of the unanticipated issue or incident, including details of how the researcher dealt with the situation.
3. The researcher usually does not need to report to the REB minor deviations from the research (such as a slight increase or decrease of testing time, a wording adjustment on a survey question, etc.).

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F. Review of Off-Campus Research

1. SAIT's jurisdiction to prohibit a member of the SAIT community from conducting research which is subject to the ethics review process contained in this procedure is not diminished by the fact that the research project might be conducted off-campus, whether in Alberta, in Canada or elsewhere. Such research shall be subject to prospective ethics review both by the researcher's REB and by the applicable ethics board or process, where such exists, with the legal responsibility and equivalent ethical and procedural safeguards where the research is to be conducted.

G. Review of Multi-Centered Research

1. In the proposal for ethics review, a researcher must identify if the work being done involves multi-centered research. To facilitate the coordination of ethics review, when submitting a proposal, the researcher may wish to distinguish between core elements of the research – those elements that cannot be altered without invalidating the pooling of data from participating institutions - and those elements that can be altered to comply with local requirements without invalidating the research.
2. Where research involves two or more REBs, SAIT's REB will coordinate its review of multi-centered projects, communicate any concerns it may have with other REBs reviewing the same project, and coordinate with other REBs in a timely and effective manner regarding the respective approval processes.

ASSOCIATED DOCUMENTS

Schedule A	Research Ethics Board Terms of Reference
Schedule B	School/Department Review Committees

POLICY/PROCEDURE REFERENCE

AC.4.4	Human Research policy
AC.4.4.2	Free and Informed Consent procedure
AC.4.4.3	Privacy and Confidentiality procedure

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