

Saint Mary's University Research Ethics Board (SMU REB)

STANDARD OPERATING PROCEDURES FOR COMPLETING REQUESTS FOR RESEARCH ETHICS REVIEW INVOLVING HUMANS

1. Government of Canada: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2, 2018)

Before undertaking any research with human participants, the researcher must be thoroughly familiar with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2, 2018): https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html

Applicants are advised to complete the online interactive tutorial, CORE- 2022 Course on Research Ethics: <https://tcps2core.ca/welcome>

2. SMU REB Initial Research Ethics Review Requirement

The Government of Canada's Panel on Research Ethics created the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2, 2018) that requires that all SMU research proposals (student, faculty, adjunct professors, administrators, employees and other persons holding appointments by the Board of Governors) that involve human participants, and fall under the TCPS2 be brought before the REB for initial research ethics review and clearance. The requirement relates to funded as well as unfunded research studies. SMU researchers must hold a valid Certificate of Research Ethics Clearance from the SMU REB in order to conduct such research. (Related reading: *TCPS2, Article 2.1.*)

3. Research exempt from REB review and activities not requiring REB review

Some research and activities are exempt from or do not require REB review. Please seek the opinion of the REB when needed by submitting a Request for Exempt Review form. Requests for exempt review are submitted to ethics@smu.ca. (See submission criteria Page 3, #6.) (Related reading: TCPS 2, Article 2.6.)

4. Certificate of Research Ethics Clearance and Certificate of Continuation for Research Involving Humans

Research studies must undergo initial research ethics review and receive clearance from the SMU REB before any participant recruitment or data collection begins. Whether a research is funded or unfunded, in order to obtain a Certificate of Research Ethics Clearance from the SMU REB; the research must comply with the policies and guidelines of the Tri- Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2, 2018) and the SMU REB.

A Certificate of Research Ethics Clearance for research involving humans is issued once research ethics clearance is obtained. The certificate is normally valid for 1 year (365 days) from the approval date after which it automatically expires unless the researcher extends the clearance for subsequent years. SMU REB certificates are submitted along with theses and MRPs. Researchers must ensure that their research records are in good standing with the Office of Research Ethics and that all continuing research ethics review responsibilities have been met.

Upon extension of ethics clearance, a Certificate of Continuation for Research Involving Humans is issued and it is normally valid for 1 year (365 days). Requests for extensions must be submitted 30 days prior to expiry of the clearance.

4. Initial Research Ethics Review Submission Requirements

(Relating reading: TCPS 2, Article. 6.11)

Requests for initial research ethics review are submitted to ethics@smu.ca.

The application for initial research ethics review consists of **either**:

Form 1 **Application for Ethics Review of Research Involving Humans**
Faculty/Student/Staff

Form 1C **Application for Ethics Review of Research Involving Humans**
Currently Cleared by Another Canadian REB
Faculty/Student/Staff research

An application must contain:

1. Form 1 (whether 1 or 1C).
2. Informed Consent Form(s)/Script(s).
3. Other supporting documents as relevant to the proposal. A listing of common materials enclosed for review appears on Form 1.

5. Continuing Research Ethics Review Requirements

(Related reading: TCPS 2, Article 6.14)

Requests for continuing research ethics review are submitted to
ethics.continuingreview@smu.ca

New Information and Unanticipated Issues (TCPS 2, Article 6.15)	Report of New Information Unanticipated Issues Required to report new information and unanticipated issues immediately, <u>no later than 1 business day</u> .
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Form 2 (TCPS 2, Article 6.16)	Request for Changes to Approved Research Required for any modifications to previously cleared research projects. Researchers must submit Form 2 when the research deviates from what the REB cleared. Consult the Office
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of Research Ethics with questions relating to the changes.

Annual Status Report

Form 3

(TCPS 2, Article 6. 14)

Required for the continuing review and the annual renewal of any previously cleared research project. Submit a Form 3, 30 days prior to the study's expiry to request the extension. A Certificate of Continuation for Research Involving Humans is issued.

Form 5

(TCPS 2, Article 6. 14)

End of Study Report

Required when the research has completed. The time of completion is normally when all data have been collected from research participants, no further contact including feedback will be made and data are recorded and stored in accordance with the provisions of the cleared application. The completion of a study is a change in activity and must be reported to the REB, otherwise either a Form 3 or a Form 5 is needed.

6. Review request requirements involving Request for Exemption review, Initial and Continuing Research Ethics Review

The SMU REB accepts requests for review work, only when the following criteria is met:

1. For student research, requests are sent by the Faculty Supervisor. For faculty and staff research, requests are sent by the Faculty of Staff Principal Investigator. Staff investigators must submit applications for initial research ethics review with a faculty supervisor or demonstrate to the SMU REB that they have sufficient expertise to conduct a particular type of research independently.
2. All request form fields are completed (no field appears blank, "n/a" is inserted when applicable).
3. Request for Exempt Review and initial research ethics review request forms, Form 1 and Form 1C, require the electronic but personally handwritten signatures of each SMU-affiliated investigator. Those who are not affiliate to SMU do not need to sign Form 1 or Form 1C.
4. All materials requiring SMU REB review are attached (consider submitting a total of 2 attachments: 1. Request SMU REB form and 2. All relating research materials.)
5. Requests are sent in one cohesive package by email to ethics@smu.ca for requests involving initial research ethics review and to ethics.continuingreview@smu.ca for requests involving continuing research ethics review.

7. Non-compliance

The SMU REB is obligated to report any cases in which a research study does not hold a valid Certificate of Research Ethics Clearance or a valid Certificate of Continuation to the Dean of Graduate Studies and Research under the provision of the Saint Mary's University Senate Policy on Integrity in Research and Scholarship and Procedures for Reporting and Investigating Scholarly Misconduct:

<http://fgsr.smu.ca/documents/SenatePolicyStatementonIntergrityinResearchandScholarship.pdf>