

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 (TCPS 2, 2022)*

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 (TCPS 2, 2022)*: https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html

Applicants are advised to complete the online interactive tutorial, TCPS 2: CORE- 2022 (Course on Research Ethics): <https://tcps2core.ca/welcome>

2. Research Exempt from Research Ethics Board Review and Activities Not Requiring Research Ethics Board Review

Some research and activities are exempt from or do not require REB clearance. 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 and verifies whether a clearance is needed. (Related reading: TCPS 2, Article 2. 2- 2.6.)

3. Research Requiring Research Ethics Board Review

The Government of Canada's Panel on Research Ethics created the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2, 2022)* 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 TCPS 2 be brought before the REB for initial research ethics review and clearance prior to recruiting participants into the research. 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, including recruitment. (Related reading: *TCPS 2, Article 2.1.*)

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

Research studies must receive clearance from the SMU REB before any participant recruitment or data collection begins. In order to obtain clearance certificates from the SMU REB, the research must comply with the articles and applications of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2, 2022)* and the SMU REB.

A Certificate of Research Ethics Clearance for research involving humans is issued once research ethics clearance is obtained from an REB Chair. The certificate is generally valid for 1 year (365 days) from the clearance 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 are responsible for ensuring that their research records are in good standing, that all continuing research ethics review responsibilities are met on time and that requests meet the REB's review request criteria. A Certificate of Continuation for Research Involving Humans is issued and it is generally valid for 1 year (365 days). Requests for extensions must be submitted 30 days prior to expiry of the current clearance.

5. Submission Requirements for Initial Research Ethics Review

(Relating reading: TCPS 2, Article. 6.11)

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

Request for Exempt Review Form

TCPS 2,
Articles 2.2-2.6

Request for Exempt Review

Required to request clearance exemption status or when seeking the assistance with interpreting the applicability of the TCPS 2.

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

Form 1

TCPS 2, Article 2.1

Application for Ethics Review of Research Involving Humans

Faculty/Student/Staff

Form 1C

TCPS 2, Article 2.1

Application for Ethics Review of Research Involving Humans Currently Cleared by Another Canadian REB

Faculty/Student/Staff research

An application for initial research ethics review 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 research materials enclosed for review appears on Form 1.

6. Submission Requirements for Continuing Research Ethics Review

(Related reading: TCPS 2, Article 6.14)

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

Report of New Information and Unanticipated Issues

TCPS 2, Article 6.15)

New Information Unanticipated Issues

Required to report new information and unanticipated issues immediately, no later than 1 business day.

Form 2

(TCPS 2, Article 6.16)

Request for Changes to Cleared Research

Required for any modifications to previously cleared research projects. Researchers must submit Form 2 when the research deviates from what the REB cleared.

Form 3
(TCPS 2, Article 6. 14)

Annual Status Report

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 review. 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 generally 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 and reviewed by the REB, otherwise a Form 3 is needed.

7. Review request submission requirements for Initial and Continuing Research Ethics Review

Researchers demonstrate the full currently known intentions about a proposal via request forms. Forms request sufficient information needed for the purposes of REB evaluation and serve as the research records to be later used for communication with researchers, routinely at the time when researchers request changes to previously cleared intentions, and for the duration of the life cycle of the research with research participants.

Serving the responsibilities having to do with the duty to provide research participants with full information and transparency, the requirements of the TCPS and the University, the REB will accept requests for its 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 or staff principal investigator. Staff investigators must submit applications for initial research ethics review with either a faculty supervisor or demonstrate to the SMU REB that they have sufficient expertise to conduct a particular type of research independently by submitting a CV to be vetted.
2. All request form fields on the form are completed (no field appears blank, "n/a" is inserted when applicable).
3. The initial research ethics request forms, Request for Exempt Review, Form 1 and Form 1C, require the electronic but personally handwritten signature of every SMU-affiliated investigator. Those who are not affiliated to SMU do not need to sign Form 1 or Form 1C. Auto-generated signatures are not accepted.
4. Form 1C and their later Annual Status Reports must accompany a copy of the current REB clearance letter or certificate issued by the other Canadian REB.
5. All research materials requiring SMU REB review are attached (consider submitting a total of 2 attachments: 1. SMU REB request form and 2. All relating research materials.)
6. Requests are sent in one bundle using the format that allows for accessibility throughout the life cycle of the research by email (i.e., without the use of cloud folders, folders and links). Only PDF and Word documents are accepted. Scanned request forms (Request for Exempt Review Form, Form 1, Form 1C, Form 2, Form 3 and Form 5) are not accepted).

7. Some Continuing Research Ethics Review requests require the submission of a new SMU REB Form 1 in order for the research to receive review in accordance with the current version of the TCPS. In such cases, the TCPS has significantly changed since the last review and the REB does not hold sufficient information about the research in order to perform a review and provide the necessary clearance at the time of the request. These instances may involve routine Annual Status reports, Requests for Changes to Cleared Research or instances that involve a researcher's transfer between institutions wherein their home Board 1 oversight review Board duties are transferred to the SMU REB and current REB clearance from another Canadian REB is no longer available to the researcher for a particular study. Applicants will be notified whenever additional information or forms are needed for a review and are encouraged to contact the REB with preparation questions.

8. 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 the day after the expiry of the research ethics clearance 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*.

Based on the practice of this policy, the REB may not review any new incoming requests, until matters are resolved. Requests received after the expired research ethics clearance experience significant delays, additional duties, may alter in the type of review that is required. The prior REB clearance period of an expired clearance, as set by the REB during its preceding review, will discontinue and the applicable new clearance period will be set.