

Saint Mary's University Research Ethics Board (SMU REB) PROCEDURES FOR COMPLETING REQUESTS FOR ETHICS REVIEW

PREFACE

1. Government of Canada: Panel of Research Ethics (PRE)

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):

<http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>

Applicants are advised to complete the online interactive tutorial, CORE, for the TCPS 2:

<http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/>

2. SMU REB Review Requirement

The Government of Canada's Panel on Research Ethics created the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) and requires that all SMU community (student, faculty, adjunct professors, administrators, employees and other persons holding appointments by the Board of Governors) research proposals that involve human participants and fall under the TCPS 2 be brought before the REB for review and approval. Researchers must have a valid Certificate from the REB.

3. SMU REB Review Exemption

Some research is exempt from REB review. Please review the relevant policy in the

TCPS 2: Chapter 2, Section A, Articles 2.2-2.6 <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/#toc02-1> to determine whether your research may be exempt from review and seek the opinion of the REB whenever there is any doubt.

4. Certificate of Ethical Acceptability/Continuation for Research Involving Humans

Research protocols must undergo ethics review and approval by the SMU REB before any participant recruitment, contact with participants or data collection begins. Whether a research is funded or unfunded, in order to obtain a Certificate of Ethical Acceptability from the SMU REB; the research must comply with the policies and guidelines of the:

1. Tri- Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2)

http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf

2. Saint Mary's University Senate <http://www.smu.ca/policy/welcome.html>

3. Saint Mary's University Research Ethics Board <http://www.smu.ca/academic/reb/>

A Certificate of Ethical Acceptability for Research Involving Humans is issued once ethics approval is obtained. This Certificate is normally valid for 1 year (365 days) from the approval date after which it expires unless the researcher renews the approval or notifies the REB that the research is complete. Researchers must ensure that their files are in good standing with the Office of Research Ethics. Upon renewal a Certificate of Continuation for Research Involving Humans is granted.

4. SMU REB Pre Approval Submission Requirements

FORM: Form 1- Application for Ethics Review of Research Involving Humans

The initial application consists of **either**:

Form 1A - Faculty Research (1 original plus 3 copies)

Form 1B - Student Research (1 original plus 3 copies)

Form 1C- Faculty/Student Research Already Approved at Another Institution

(1 copy + application submitted and approved at the other institution + ethics approval certificate/letter from the other institution + any comments/concerns from the other institution's REB.)

Each application package must contain:

1. The appropriate research proposal form (whether 1A, 1B or 1C).
2. Informed Consent Form(s)/Script(s).
3. Other supporting documents as relevant to the proposal: For example, copies of the questionnaire, survey, draft of interview questions, feedback form, invitation letter, telephone script, advertisement, flyer, etc.

Applications that are incomplete or that are submitted electronically will not be processed until received correctly.

5. SMU REB Post Approval Reporting Requirements

Adverse Event

Form Adverse Event Report

Required to report any and all adverse events immediately, no later than 1 business day. Adverse Event Reports are reviewed by the full Board. Adverse Event Policy:

<http://www.smu.ca/academic/reb/policies.html>

Form 2

Modifications to Previously Approved Proposals

Required for any modifications to previously approved research projects. Researchers must submit Form 2 when the research deviates from what the REB approved. Only 1 copy is required. Electronic submission by the SMU faculty researcher is acceptable.

Form 3

Annual Renewal Request for Previously Approved Projects

Required for continuing review and the annual renewal of any previously approved research projects. Submit a Form 3 30 days prior to the study's expiry to request an extension. Only 1 copy is required. A Certificate of Continuation for Research Involving Humans is granted. Electronic submission by the SMU faculty researcher is acceptable.

Form 4

Annual Course Renewal Request for Previously Approved Course Projects

Required for continuing review and the annual renewal of any previously approved projects. Submit a Form 4 30 days prior to the study's expiry to request an extension. Only 1 copy is required. A Certificate of Continuation for Research Involving Humans is granted. Electronic submission by the SMU faculty researcher is acceptable.

Form 5

Completion of Research

Required when the activity has completed and participants are no longer at risk. The time of completion would normally be 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 approved 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 will be requested. Only 1 copy is required. Electronic submission by the SMU faculty researcher is acceptable.

6. Non-compliance

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

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