



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

Standard Operating Procedure (SOP) REB Review Criteria

1. PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the SMU REB review submission requirements and review procedures. This SOP applies to both initial and continuing REB review requests. When the review criteria are met, the request is registered for review work, received a SMU REB file number to later reference and the review work of the current research plan begins.

2. REB REVIEW

2.1. Review Jurisdiction

- 2.1.1. The SMU REB is the review Board for Saint Mary's University and NSCAD University.
- 2.1.2. The appeals review Board for the SMU REB is the Mount Saint Vincent University REB.

3. DEMONSTRATION OF THE CURRENT RESEARCH PLAN

Researchers demonstrate the full currently known intentions about a research plan via request forms. Forms request the sufficient information needed for the purposes of REB review. The plan will serve as the research record to be later used for communication with research participants, researchers and routinely referenced when researchers request changes to a cleared plan when new plans emerge. The REB will provide review service throughout the life cycle of the research. REB review and clearance is needed in order to invite potential participants to take part in the research. The design of the research plan is at the liberty of researchers and is outside of an REB's purview. An REB review considers the ethical relevance of the current research plan.

4. TYPES OF REB REVIEW

4.1. Initial REB Review

4.1.1. Request for Exemption Review

Exemption review results tell researchers either: that according to the TCPS 2 (2022), the current plan is not deemed "research" with human participants or that a request for initial REB review needs to be sent along. This opinion seeking is optional but is advised as the Step 1 interaction with the REB.

4.1.2. Demonstration of the Current Research Plan for Initial REB Review

Initial review clearances of the current research plan tells researchers, "Recruitment of research participants may begin with a ready informed consent process."

4.1.3. Demonstration of the Current Research Plan for Initial REB Review Cleared by Another Canadian REB

Initial local review clearances of the current local research plan tell researchers, "Until the other Canadian REB clearance is in place, recruitment of research participants for the SMU-affiliate may begin."

4.2. Continuing REB Review

4.2.1. Report of New Information and Unanticipated Issues

Continuing review clearances of a new information and unanticipated issues report tell researchers, "This is the best way to proceed in light of the new information or event." Some or no alternations may be needed to the research plan moving forward but a discussion is needed.

4.2.2. Request for Change to a Cleared Research Plan

Continuing review clearances for changes to a cleared research plan tell researchers, "research with participants may continue with the newly demonstrated additions".

4.2.3. Annual Status Report

Continuing review clearance of an annual status report tell researchers, "The research holds extended clearance for another full year."

4.2.4. End of Study Report

Continuing review clearance of an end of study report tell researchers, "The research has completed in a manner that aligns with the promises that have been made to participants."

5. REB REVIEW CRITERIA

The duty is to provide research participants with full information and transparency about the known current research plan and the consent process must be comprehensive and meaningful to the particular research participant(s). These are requirements of the TCPS 2, 2022, the University and the REB. The REB will maintain a master file for the research and serves as a contact to research participants as designated by the TCPS and by the researchers. In order for the REB to be situated as a proper contact, the REB will accept requests for REB review only if when the following criteria is met. The criteria allow the heavy workload of the REB to be continuous and smooth.

- 5.1. The request is submitted to the correct location. For Initial REB review, the request is submitted to ethics@smu.ca. For Continuing REB review, the request is submitted to ethics.continuingreview@smu.ca.

- 5.2. The faculty supervisor submits the request for student research. The faculty or staff principal investigator submits the request for faculty and staff research. A staff investigator submits the request either with a faculty supervisor or demonstrates to the REB that they have sufficient expertise to conduct the research independently by submitting a CV to be vetted by the Dean of Faculty and Graduate Studies and Research/Associate Vice President of Research.
- 5.3. All requests are fully filled with “n/a” inserted, when applicable. No question fields appear blank for the review work.
- 5.4. SMU- affiliated researcher sign the request for Initial REB review.
- 5.5. SMU-affiliated researcher signatures are personal signatures. An accepted signature is electronic but is personally drawn. Auto-generated signatures generated by the system in not accepted.
- 5.6. All research materials requiring REB review are attached. A total of two attachments is considered (1. REB review request form and 2. Research materials: recruitment material, informed consent form/script, interview plans, research questions, surveys, feedback letter, debriefing letter, external clearance letters, and as applicable to the particular research.)
- 5.7. Current external REB clearances are attached to the review request at the time of submission to the SMU REB. Other required research licenses are explained in the Initial REB review request form.
- 5.8. The request for REB review is sent only using PDF and Word. External folders, cloud folders and scanned document are not accepted.
- 5.9. The technical contact for the REB is the Software and Application Support Lab (SAS) at sas@smu.ca. Researchers work directly with the lab for skill learning and station related support. The REB review request form is regular Adobe Reader that is opened by regular Adobe Reader and is updated by the University automatically on all SMU stations. Home stations/laptops may not be automatically updated by the University. The free non-trial version of the update that is provided during SAS consultations is: https://get.adobe.com/reader/?_branch_match_id=860199318184484959
- 5.10. Some request for Continuing REB Review may require the submission of a new Demonstration of the Current Research Plan for Initial REB Review form when prompted by the newest version of the TCPS. In such cases, the TCPS has significantly changed and the record on file does not contain sufficient information for the REB review and the necessary oversight and clearance at the time of the new request.

These instances may involve a routine Annual Status Report, Request for Change to a Cleared Research Plan, a researcher's transfer between institutions wherein the former Board 1 oversight review Board duties are transferred to the SMU REB and current REB clearance from a former or other REB is no longer available to the researcher for a study. Researchers are notified whenever additional information or request forms to supply sufficient informant necessary for REB review are needed and are encouraged to contact the REB with preparation questions.

6. TYPE OF REB REVIEW CLEARANCE CERTIFICATES

6.1. Initial REB Review

6.1.1. In order to obtain a REB Review clearance certificate, the research plan must comply with the articles and applications of the TCPS 2, 2022 and applicable University and SMU REB Policies and Practices. A Certificate of Research Ethics Clearance for Research Involving Humans is issued once the clearance is obtained from an REB Chair. The clearance is generally valid for 1 year (365 days) from the clearance date after which it automatically expires.

6.2. Continuing REB Review

6.2.1. Researchers can renew the clearance period for the research for subsequent years by submitting an Annual Status Report 30 days prior to the clearance end date's expiration date. A Certificate of Continuation for Research Involving Humans is issued for extensions.

7. NON-COMPLIANCE WITH REB REVIEW

7.1. Compliance Practices

7.1.1. The REB is obligated to report any cases in which a research study does not hold a valid Certificate of Research Ethics Clearance for Research Involving Humans or a valid Certificate of Continuation the day after the expiry of the clearance to the Dean of Graduate Studies and Research/Associate Vice President of 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.

7.1.2. Based on the practice of the policy, the REB may not review any new incoming or active requests, until matters are resolved. Requests received after the clearance expiry experience significant delays, additional REB review duties and may alter the type of REB review that is required.

7.1.3. The prior REB clearance period for an expired clearance, as set by the REB's prior Initial or Continuing REB review, will discontinue and the applicable new clearance period is set.