



Saint Mary's University Human Research Ethics Board (SMU HREB)

REB Review Criteria Standard Operating Procedure (SOP)

I. PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the SMU REB review submission requirements and review procedures to SMU member, the REB and those who request REB review service. This SOP applies to both Initial REB Review and Continuing REB Review requests. When the review criteria are met, the request is registered by the REB for review work. SMU REB review and clearance is required in order to invite potential human research participants to take part in SMU research. SMU research involves a SMU-affiliate.

The relating Canadian policy is the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, (TCPS 2, 2022)*. Previous versions of the TCPS were 1998, 2010, 2014 and 2018. Researchers must ensure they are using the correct version of the policy during their preparations. The official version of the policy is the online version from the Panel on Research Ethics: https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html

II. REB REVIEW

1. Review Jurisdiction

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

2. REB Communication

The directives and the language that are included in all communication are requirements and constructions of the SMU REB and the Dean of Research. All communication is initiated from groups (ethics@smu.ca/ fgsr@smu.ca division) versus individual employee firstname.lastname@smu.ca, REB personnel, Co-Chair, Vice-Chair or member.

3. Comprehensive Research Plan Record Keeping

Comprehensive research plan records include all documentation related to a project. The plan is submitted to the REB for research ethics review work. The records are used for communication with research participants, the REB, and

researchers throughout the life cycle of a research. The REB maintains a master file of the original as well as all subsequent project intention(s). Researchers maintain a copy of their research plans and are encouraged to use version numbers that make clear to research participants, the REB and researchers which version of a plan is being discussed, has received clearance, and which version of a plan is a new request. This type of practice enables review work to run both sufficiently and smoothly.

4. Demonstration of the Current Research Plan

The REB provides review service throughout the life cycle of the research.

In order for the REB to provide review service, researchers demonstrate the full currently known research plan via request forms (Form 1/Form 1 C). Forms request the sufficient information needed for the purposes of REB review. What information is required for REB review in Canada is updated from time to time. Researchers must use the most recent version of the request forms directly from the REB website. This ensures that the most up-to-date request form is filled for review work.

This 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 whenever new plans emerge. An REB review considers the ethical relevance of the current research plan as demonstrated.

The design of the research plan is at the liberty of researchers and is outside of an REB's purview.

5. Types of REB Review

5.1. Initial REB Review

5.1.1. Request for Exemption Review

Exemption review results tell researchers, **either**: a) that according to the TCPS 2 (2022), the current plan is not deemed "research" with human participants; **or** b) that the current plan needs to be submitted for Initial REB Review via a Request for Exemption Review form.

A request for Exemption Review is optional. It is advised as the Step 1 interaction with the REB, and a preferred step by researchers because a formal and up-to-date REB evaluation is secured. Separate additional Exemption Reviews are submitted whenever there are any alternations to the latest Exemption Review for a second/different formal evaluation. The REB evaluation cannot be provided via an in-person or via email communication. The evaluation is provided based on what has been demonstrated in the request.

5.1.2. Form 1: Application for Research Ethics Clearance for Research Involving Humans

Initial review clearances of the current research plan tells researchers, "Recruitment of research participants may now begin with a ready informed consent process." Subsequent changes to this version of the research plan, to include any changes to research material(s), receive REB review via a Change to a Cleared Research Report.

5.1.3. Form 1 C: Application for Research Ethics Clearance for Research Involving Humans with Current Clearance 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." Evidence of the current external clearance to the SMU REB is required. When no external clearance exists or external clearance ceases to exist, the SMU REB becomes the primary review Board and a request for Initial REB Review via a Form 1 is required.

5.2. Continuing REB Review

5.2.1. New Information and Unanticipated Issues Report

Continuing review clearances of a new information and unanticipated issues report tell researchers, "This is currently 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.

5.2.2. Change to a Cleared Research Report

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

5.2.3. Annual Status Report

Continuing review clearance of an annual status report tell researchers, "The original research ethics clearance period is extended and the research holds clearance for another full year as specified." The research ethics clearance automatically expires unless a request for review is submitted on time.

When the prior REB clearance was provided by another Canadian Reb (other than the home SMU REB) the document evidencing the current research ethics clearance by the other Canadian REB must accompany the Annual Status Report. The home SMU REB will work in accordance with the present clearance period.

When no external clearance exists or external clearance ceases to exist, the SMU REB becomes the primary review Board and a request for Initial REB Review via a Form 1 is required.

5.2.4. 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." The end of study report review is the end stage for REB review requirement.

6. REB Review Criteria

The duty is to provide research participants with full information and transparency about the currently known research plan. The consent process must be comprehensive and meaningful to the particular research participant(s) to whom the invitation to take part in the research is extended. These are requirements of the TCPS 2, 2022, Article 3.2. Consent Shall Be Informed, the University and the REB.

The REB maintains a master file for the research and serves as a contact to research participants as designated by the TCPS and by researchers during the course of the consenting process. 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 allows the heavy workload of the REB to be continuous and smooth. The criteria has also been developed and is continuously developed based on the needs of the research community and the common errors experienced during submission. All applicants must review and work in accordance with the elements of the REB Review Criteria.

When requests arrive to the REB incomplete, it is often one or maximum a few items that are missing from the criteria listing. Characteristics of a complete request are listed below.

Not enclosing recruitment material(s) is common. Recruitment material(s) require REB review , clearance and will include a SMU REB clearance number on them, prior to their use with potential research participants.

- 6.1. 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.
- 6.2. The faculty supervisor submits the request for student research.
- 6.3. The faculty or staff principal investigator submits the request for faculty and staff research.
- 6.4. 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 independency by submitting a CV to be vetted by the Dean of Faculty and Graduate Studies and Research/Associate Vice President of Research. When the qualification is vetted, the REB can begin the review work.
- 6.5. Requests (and resubmissions, when applicable) are compiled by the Principal Investigator/Faculty Supervisor (involving student research) as intended for REB

review work. The REB does not retain copies of partial and incomplete requests or compile requests when submitted in a piecemeal fashion. This accomplishes that correct versions of documents are undergoing review work as directly intended by the requestor(s).

- 6.6. The request is sent only using PDF and Word. External folders, compressed folders, cloud folders and scanned document are not accepted. This practice protects readability and availability of the documents throughout the life cycle of the research and is a requirement for REB review work. When the REB is able to access, circulate and retain research materials, it is sufficient. New formats for transferring data to the REB emerge. Applicants are advised to check during the preparation stages with the REB (via ethics@smu.ca) whether documents can be accessed on the receiving end.
- 6.7. Documents are titled exactly how they are referenced in the methods section of the request forms. I.e., “Informed Consent Form- Group 1”, “Recruitment Email- Group 3” or “Interview Questions- Group 1 of 4”. Applicants are advised against using slang, student names, “clean”, “final”, “draft” in the document name and to consider combining all documents in one document ensuring that content on pages is not cut off or missing.
- 6.8. All research materials must be fully and promptly accessible to the REB during the duration of the research’s life cycle at any given time. The REB serves as the ethical contact to research participants and can only accept materials that will appropriately situate the REB to perform this responsibility. REB and researchers work to accomplish having two sets of the same version of research materials last cleared by the REB on hand and readily available.
- 6.9. A total of two attachments is considered: 1. REB review request form/report that convey the plan and 2. All research materials for the research: recruitment material, informed consent form/script and research instruments relating to the plan.
- 6.10. All requests are fully filled with “n/a” inserted, when applicable. No question fields appear blank or as “choose one”.
- 6.11. Required research license(s) are attached and explained in the Initial REB Review request form, Form 1- Application for Research Ethics Clearance for Research Involving Humans, and when subsequently applicable, the research’s upcoming Annual Status Report.
- 6.12. The home SMU REB requires that applicants supply evidence of the Mi’kmaw Ethics Watch (MEW) opinion in order to register a request for SMU REB review work. The MEW review is necessary and primary. The MEW review criteria is distinct to MEW environments. The opinion is provided either in the form of an exemption or a clearance from mew@cbu.ca.

MEW opinion arrives to researchers in the format of an email directly from MEW conveying the result of the review. This is the communication to send along to the SMU REB together with the review request. Researchers hear back from MEW about these type of questions quite quickly. In large part, the review involves matters surrounding collective knowledge, demographic capture, its extend and its types. When MEW clearance is applicable, evidence of clearance is required in order for the SMU REB to register a request for review work.

- 6.13. Required research clearances from external school/hospital/agency/REB body relating to multi-jurisdictional/international research, police, Navy, First Nations, Inuit, Metis, community group, data holder agreement, letter(s) of supports, and as otherwise relevant to the research are attached and explained in the Initial REB Review request form, Form 1- Application for Research Ethics Clearance for Research Involving Humans, and when subsequently applicable, the research's upcoming Annual Status Report. It is rare, but possible, that researchers may submit a review request to the REB without a relating clearance. In such circumstance, researchers must explain to the REB the reason that a relating clearance is not submitted at the time of the application so the REB can assess whether review work can begin. Without an explanation supplied, the REB will request the information, and review work may be delayed in the interim.
- 6.14. The current external REB clearance is attached to the review request to the home SMU REB involving a Form 1 C- Application for Research Ethics Clearance for Research Involving Humans with Current Clearance by Another Canadian REB; and when subsequently applicable, the research's upcoming Annual Status Report. This is because the Initial REB Review and clearance is from another Canadian REB that SMU-affiliated researchers are asking for the home SMU REB to consider in the SMU REB review work.
- 6.15. Applicants itemize all research materials involved in the proposal requiring REB review, number and title each document as referenced on the request form. Applicants are requested to utilize the "listing of additional proposal specific materials enclosed for REB review", the "additional information relating to the materials enclosed for REB review" and the "additional information" section of Form 1 to make clear to the REB what materials are involved in the research that require REB review.
- 6.16. The recruitment material(s) is attached.
- 6.17. The informed consent form/script(s) is attached.

- 6.18. Research instruments such as screening, demographic, survey, focus group guide, auditory/visual stimuli, individual or group interview plans, supplementary tables or figures, interview questions, and as relevant to the particular research; are attached.

A helpful way to think about this is that all materials that research participants are proposed to be exposed to, and all relating research plans relating the study plan must undergo REB review.

- 6.19. Feedback/debriefing materials such as letters, scripts to participants and participant's parent/guardian/proxy (when applicable) are attached.
- 6.20. SMU- affiliated researcher(s) sign the request for Initial REB review. The signatures are personal signatures. An accepted signature is electronic but is personally drawn. Auto-generated signatures generated by the system in not accepted.
- 6.21. Some request for Continuing REB Review may require the submission of a new Form 1- Application for Research Ethics Clearance for Research Involving Humans for Initial REB Review 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 current REB review at the time of the incoming request.

These instances may involve a routine Annual Status Report, Request for Change to a Cleared Research Plan, a researcher's transfer between institutions or other circumstances researchers may plan or experience wherein the former Board 1 (external REB) oversight duties are transferred to the SMU REB thereby a current REB clearance from a former REB is no longer available to the researcher for a study.

- 6.22. The REB is responsible for maintaining and disseminating review requirement information to researchers. Researchers are notified whenever additional information or request forms are necessary for a REB review and are encouraged to contact the REB with preparation questions. The REB reserves the right to delay consideration of requests that lack information critical to the REB review work.

It is common that the first work together with the REB is discussing the contents of the proposal submission versus discussing the ethical evaluation of the proposal. The REB will follow up with the Principal Investigator/Faculty Supervisor to request the required information for inclusion for REB review work. Only completed requests are considered for delegated and full Board review work.

- 6.23. Not all browsers are compatible with fillable PDF forms. Depending on the browser applicants are using, they may see different results when attempting to complete a fillable PDF because of the built-in PDF viewer. Adobe Reader is the only program that will allows work with the form properly. This way, user and reader will be able to access the information on the form. Mac and Chrome users should not use

Preview. Applicants should save the form (PDF format) to drive or location on their computer by right clicking the PDF and select “Save as” or “Save page as”. After the form is completed, applicants should save the final version of the file to their computers to allow later access and editing, should applicants need, (See 6.22.)

- 6.24. The technical contact for the REB is the Software and Application Support Lab (SAS) at sas@smu.ca. The REB does not serve as a technical contact. The REB and researchers work directly with the lab for skill learning and station related support. The SAS lab provides and cowrites directives provided to researchers and flags any technical issues to the REB.

REB review request forms are 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

- 6.25. Applicants are advised to save a copy of their draft application to allow any later edits to the same form, should applicants need to adjust the plan at any time or when resubmitting a request.
- 6.26. A SMU REB file number is assigned to each request for the research participants, the REB and researchers to reference in all communication, and the review work of the current research plan begins.

7. Type of REB Review Clearance Certificates

7.1. Initial REB Review (Application Form 1/Form 1 C)

- 7.1.1. In order to obtain a REB Review clearance certificate, the research plan must comply with the articles and applications of the TCPS 2, 2022, 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. When Initial REB Review was obtained by an external REB, the SMU REB aligns with the external REB’s clearance end period.

7.2. Continuing REB Review

- 7.2.1. 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 that supplies the new research ethics clearance

period. When Initial REB Review was obtained by an external REB, the SMU REB aligns with the external REB's clearance end period.

8. Research Funding

The REB reports the funding details of a review request to the Research Grants Officer on behalf of the researcher exactly as reported to the REB. The information is required to release the research funds. Any changes to funding must be promptly reported to the REB throughout the life cycle of the research. Researchers discuss funding related questions directly with the Research Grants Officer.

III. COMPLIANCE WITH REB REVIEW

1. Compliance Practices

- 1.1. The REB does not grant post hoc research ethics clearance. Research ethics clearance must be obtained prior to conducting a research. This includes recruitment/inviting potential human research participants to part take in a research.
- 1.2. It is the researcher's responsibility to remain compliant with the REB.
- 1.3. The REB sends a courtesy reminder before a clearance expires to the researcher conveying the option to request a clearance extension or completion review of a research.
- 1.4. 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.
- 1.5. Based on the practice of the policy, the REB may not review any new incoming or active requests, until matters are resolved.
- 1.6. Requests received after the clearance expiry experience significant delays, additional REB review duties and may alter the type of REB review that is required.
- 1.7. 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.