Research Ethics Board

Standard Operating Procedure

Document Number	**REB.SOP.301**
Title	REB Submission Requirements and Document Review
Effective Date	September 23, 2021
Next Review	2026
Next Administrative Review	2023

1. **Purpose**
   This standard operating procedure (SOP) describes Research Ethics Board (REB) submission requirements and document review procedures. This SOP applies to all submissions including, but not limited to: applications for initial review, modifications or changes to approved research, renewal applications for ongoing research and completion reports.

2. **Definitions**
   See the MSVU **REB Glossary of Terms (REB.INFO.001)**

3. **Scope**
   This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

4. **Responsibilities**
   REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

5. **Procedures and/or Specific Policies**
   REB members must rely on the documentation provided by the Researcher for initial and continuing review. Therefore, the materials submitted must provide sufficient information to conduct the review and to make the required determinations.

   The REB is supported by administrative procedures that ensure that REB members not only have adequate time for the assessment of the proposed research, but that the materials they receive allow them to adequately assess whether the research submission meets the criteria for REB approval.

   The requirements for REB submissions are made available to all Researchers. The REB Office Personnel are responsible for maintaining and disseminating this information to Researchers.

5.1. Submission Requirements

5.1.1. The required documents, format and submission procedures are outlined on the REB's website. These may include:

- REB Application form,
- Continuing Review form,
- Amendment and/or Administrative Change form,
- Unanticipated and Adverse Event Reporting form,
- Research Completion form.

5.1.2 The REB may request any additional documentation it deems necessary to the ethics review, or for research ethics oversight;

5.1.3 The research question and methodology is written in sufficient detail to permit evaluation of the scientific or scholarly merit of the project. The research should include all of the required elements applicable to the research such as, but not limited to:

- Research rationale and objectives,
- Design and detailed description of methodology,
- Eligibility criteria, description of the population to be studied,
- Recruitment and consent process,
- Research interventions,
- Primary and secondary outcomes,
- Sample size justification,
- Data analysis.

5.2 Document Review Procedures

5.2.1 A unique number is assigned to each submission at the time of the receipt of the application. REB Office Personnel screens the submission for overall completeness;

5.2.2 If the submission is incomplete (e.g., documents are missing or incorrect documents were uploaded), the REB Office Personnel will follow up with the Researcher and/or alternate contact to request the required information for inclusion with the submission;

5.2.3 Upon receipt of a complete submission, the responsible REB Office Personnel identifies any outstanding items that will be required to issue approval, as applicable;

5.2.4 For submissions requiring Full Board review, the REB Office Personnel posts the submission to the agenda of the next Full Board meeting. Primary and secondary reviewers are assigned once the agenda is complete, if applicable;

5.2.5 For submissions reviewed via delegated review procedures, the REB Chair or designee assigns a reviewer(s) and sends the research to that (those) reviewer(s).

6. References

See References listed (if applicable)

7. Acknowledgements

The development of this document has benefited directly from similar documents made public by the Tri-Council, as well as several Canadian universities. In some instances, specific formulations drawn from these sources have been incorporated into this document. Specific iterations were drawn from the following:

- Standard Operating Procedures for Observational Health and Non-Clinical Trial Research Ethics Boards - N2/CAREB-ACCER REB SOPs – Canadian Association of Research Ethics Boards (retrieved July 2021)
- N2/CAREB-ACCER REB SOPs - N2 Network of Networks - Resources - N2 Canada (retrieved July 2021)

8. SOP History

SOP Number	Key Changes	Effective Date
REB.SOP.301	Original Version	September 2021

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