Research Ethics Board

Standard Operating Procedure

SOP File #	**REB.SOP.108**
Title	SOP Maintenance
Effective Date	July 1, 2021
Next Review	2026
Next Administrative Review	2023

1. Purpose

This standard operating procedure (SOP) describes the processes for establishing and maintaining written SOPs. The purpose of having written SOPs is to promote quality and consistency in the ethics review process; ensure compliance with the principles, guidelines, and regulations applicable to the ethics review and oversight of research involving humans; and facilitate training of new personnel.

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

All REB members, REB Office Personnel and Researchers are responsible for ensuring that the requirements of this SOP are met.

5. Procedures and/or Specific Policies

Written SOPs provide the framework to promote ethical standards in the review, oversight and conduct of research involving human participants. SOPs describe the processes that must be followed and documented to ensure that the rights and welfare of human participants of such research are overseen and protected in a uniform manner.

5.1. Development, Review, Revision and Approval of Policies & Procedures

5.1.1. Designated REB Office Personnel will review the SOPs at least bi-annually (once every second year). SOPs will be reviewed sooner if changes to policies, guidelines, or standard practice warrant revisions or the creation of new SOPs;

5.1.2. SOPs may be revised for reasons including, but not limited to: changes to policies, regulations or guidelines, new policies, or changes to REB or administrative practices;

5.1.3. Designated REB Office Personnel will make the necessary modifications to existing SOPs or draft a new SOP(s). SOPs are controlled documents and new

drafts will be indicated by the addition of "DRAFT version date" and removal of the previous "Final Version Date";

5.1.4. The revised SOP(s) will be circulated to REB Office Personnel and REB Chair or designee, as well as REB members and Organizational personnel (as appropriate) for review. Comments will be incorporated into a new version with an updated version date;

5.1.5. Once the SOP content is approved, the draft version date will be removed and the date the approved version will be entered as the "Final Version Date". The history of revisions will be recorded in the 'SOP History' section of each SOP;

5.1.6. Signatures on the SOP as determined by organizational policy will denote SOP approval. A new final version of the SOP supersedes any previous versions.

5.2. **Distribution and Communication**

5.2.1. New or revised SOPs and associated guidance documents will be communicated and disseminated to all individuals identified in the 'Responsibilities' section of each SOP;

5.2.2. The SOPs will be available to Researchers and research teams, Organizational personnel, sponsors, and funders as required;

5.2.3. Designated REB Office Personnel will train members of the REB and other REB Office Personnel on any new or revised policy and or relevant procedure, as applicable;

5.2.4. Each new REB member must review the applicable policies and procedures prior to undertaking their responsibilities as an REB member;

5.2.5. Each new REB Office Personnel must review the applicable policies and procedures prior to undertaking their responsibilities with the REB office;

5.2.6. Evidence of training must be documented;

5.2.7. The REB office shall maintain all documentation of SOP training.

5.3. **Forms, Memos and Guidance Documents**

5.3.1. Forms such as checklists and worksheets may be developed to facilitate compliance with the SOPs and to ensure that policies are integrated into daily operations. Forms may be either controlled or non-controlled;

5.3.2. Memos and guidance documents may be developed to provide guidance for the interpretation and implementation of the SOP;

5.3.3. Memos and guidance documents will be made available to the Researchers as applicable;

5.3.4. Designated REB Office Personnel and/or REB Chair or designee will evaluate the need for new or revised forms, memos, or guidance documents.

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 June 2021)
- N2/CAREB-ACCER REB SOPs - N2 Network of Networks - Resources - N2 Canada (retrieved May 2021)

8. SOP History

SOP Number	Key Changes	Effective Date
REB.SOP.108	Minor revisions for EDI language	July 30, 2021
REB.SOP.108	New - Implementation of new SOP outlining SOP Maintenance	July 1, 2021

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