Research Ethics Board

Standard Operating Procedure

SOP File #	**REB.SOP.402**
Title	Initial Review - Criteria for REB Clearance
Effective Date	September 23, 2021
Next Review	2026
Next Administrative Review	2023

1. **Purpose**
   This standard operating procedure (SOP) describes the minimum requirements that research proposals involving human participants must meet in order to be approved by the Research Ethics Board (REB), independent of the review pathway (i.e., Full Board or delegated review).

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

   REB members are responsible for determining whether the research meets the criteria for clearance.

5. **Procedures and/or Specific Policies**
   All research involving human participants must meet criteria before REB clearance may be granted. Initial REB clearance of the research is based on assessment of a complete submission to the REB. The REB and/or REB Office Personnel may consult the Researcher for additional information as necessary.

   Following initial review of the research, the REB should be prepared to make a determination as to the approvability of the research.

   In addition to REB clearance, the requirements of the organization where the research will be conducted must also be met before the research can begin (e.g., department approvals, adequate resources, etc.).

5.1. Minimal Criteria for Clearance of Research

In order for the research study to receive REB clearance, the REB will take, at a minimum, the following into consideration:

5.1.1. The application has been authorized by the Researcher and, if applicable, by a designated Organizational Official, indicating that the Researcher has the authority to conduct the research;

5.1.2. Any potential conflicts of interest are declared and are managed appropriately to prevent any compromises to the safety or well-being of the participants or to the integrity of the data;

5.1.3. The research will generate knowledge that could lead to improvements in health or well-being of individuals or society;

5.1.4. The methodology is appropriate with respect to the discipline and capable of answering the research question;

5.1.5. The risks to participants are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk;

5.1.6. The risks to participants (if any) are reasonable in relation to the anticipated benefits, if any, and the importance of the knowledge that will be generated;

5.1.7. The selection of participants is equitable. In making this assessment, the REB will consider the purpose of the research and the research setting. The REB will consider vulnerability of participant populations with respect to ethical reasons for their inclusion, as appropriate;

5.1.8. There are sound methodological and ethical reasons for excluding classes of persons who might benefit from the research;

5.1.9. When some or all the participants may be in situations or circumstances that make them vulnerable in the context of the research, additional safeguards have been included in the research, and in the REB review process, to protect the rights and welfare of these participants;

5.1.10. The amount and method of payment to participants is appropriate to ensure that there is no coercion or undue influence and that information regarding payment to participants including method, amounts and schedule, is provided to participants when applicable;

5.1.11. Informed consent will be sought from each prospective participant or from the participant's legally authorized representative, in accordance with and to the extent required, by applicable policies and guidelines;

5.1.12. The informed consent process will ensure the research and the required elements of consent are accurately explained to participants;

5.1.13. The informed consent process will be appropriately documented in accordance with the relevant policy;

5.1.14. There will be adequate provisions to protect the privacy of participants and to maintain the confidentiality of data;

5.1.15. There will be adequate provisions for the timely publication or dissemination of the research results, unless there is an ethically acceptable reason for withholding publication or dissemination (e.g., Indigenous community control);

5.1.16. If applicable, the research has been or will be registered via an internationally recognized clinical trial registry and a registration number has been/will be submitted to the REB. If the research is not yet registered, the researcher shall provide the REB with the registration number upon registration.

5.2. Additional Criteria

5.2.1. Studies proposing access to, or collection of, personal information require consideration of additional items to ensure the protection of the privacy of the personal information and to determine whether appropriate privacy legislation is adhered to;

5.2.2. Additional criteria for research involving Indigenous peoples in Canada, or research on materials related to human reproduction, or genetic research shall be applied when applicable in accordance with policies and/or Regulations.

5.3. Length of Clearance Period

5.3.1. The REB shall establish the length of clearance in relation to the degree of risk to participants, up to a maximum of one year;

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.402	Formerly SOP 108 (now retired); Extensively revised - Replaced with N2/CAREB harmonized SOP 402	September 2021
REB.SOP.108	Minor Revisions, pulled into unique SOP	March 2012
Section 5 & 6	Policies & Procedures: Ethics Review of Research Involving Humans (original UREB Policy Handbook)	2000

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