

SOP Title:	Initial Criteria for REB Approval		
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Approved By:	Dr. Elizabeth Stephenson		

1.0 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).

2.0 POLICY STATEMENT

All research involving human participants must meet certain criteria before REB approval may be granted. Initial REB approval of the research is based on assessment of a complete submission to the REB. The REB and/or REO 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 approval, 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.).

3.0 DEFINITIONS

See Glossary of Terms

4.0 RESPONSIBILITY

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

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

5.0 PROCEDURES

5.1 Minimal Criteria for Approval of Research

- 5.1.1 The application has been signed by the Researcher and, if applicable, by a designated Organizational Official (i.e., Department Head), indicating that the Researcher has the qualifications and resources available 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 There is a state of clinical equipoise when there is a comparison of two or more interventions;
- 5.1.4 The research will generate knowledge that could be generalized and lead to improvements in health or well-being;
- 5.1.5 The methodology is scientifically sound and capable of answering the research question;
- 5.1.6 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, and
 - By using procedures already being performed on the participants clinically for diagnostic or treatment purposes whenever appropriate;
- 5.1.7 The risks to participants are reasonable in relation to the anticipated benefits, if any, and the importance of the knowledge that will be generated;
- 5.1.8 The selection of participants is equitable. In making this assessment, the REB will take into account the purpose of the research and the research setting. The REB will consider the scientific and ethical reasons for including vulnerable populations, if applicable;
- 5.1.9 There are sound scientific and ethical reasons for excluding classes of persons who might benefit from the research;
- 5.1.10 When some or all of the participants, such as children, prisoners, the elderly, pregnant women, those with mental health issues, and those with diminished capacity for self-determination are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the research, and in the REB review process to protect the rights and welfare of these participants;
- 5.1.11 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;
- 5.1.12 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 regulations and guidelines;
- 5.1.13 The informed consent form will accurately explain the research and contain the required elements of consent;
- 5.1.14 The informed consent process will be appropriately documented in accordance with the relevant regulations;
- 5.1.15 There will be provisions for on-going data and safety monitoring procedures that are appropriate to the size, complexity, phase, and level of risk of the research. The REB may recommend the use of a Data and Safety Monitoring Board (DSMB) to enhance participant protection;

- 5.1.16 There will be adequate provisions to protect the privacy of participants and to maintain the confidentiality of data;
- 5.1.17 There will be adequate provisions for continued access to the agent or device or adequate replacement of the test agent after the research is complete, when appropriate;
- 5.1.18 There will be adequate provisions for the timely publication and dissemination of the research results;
- 5.1.19 The research has been submitted to Health Canada if applicable, and the Health Canada No Objection Letter has been issued
- 5.1.20 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 health 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 Aboriginal peoples (including Indian (First Nations), Inuit and Métis peoples) in Canada, or research on materials related to human reproduction, or genetic research, or research with groups considered vulnerable shall be applied when applicable in accordance with governing principles and/or Regulations.
- 5.2.3 For research that is subject to the provisions of 45 CFR 46 or 21 CFR 56, the REB shall consider the listed criteria in the applicable regulations, to the extent that they differ from or vary the criteria noted above.

6.0 REFERENCES

See References