SOP Title	**Initial review Criteria for HSREB**
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Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Research Ethics and Compliance		26 Jan 2022
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1. PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the minimum requirements of research proposals involving human participants for approval by the Health Sciences Research Ethics Board (HSREB), independent of the review pathway (Full Board or via Delegated review).

2. GENERAL POLICY STATEMENT

All research involving human participants must meet certain criteria before HSREB approval may be granted. The approval criteria are based on the guiding ethical principles of the Tri-Council Policy Statement (TCPS) and applicable regulations and guidelines.

Initial HSREB approval of the research is based on assessment of a complete application package. The HSREB may consult the Investigator for additional information as necessary.

Following initial review of the protocol, the HSREB 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. RESPONSIBILITY

This SOP applies to the HSREB Chair, Vice-Chair(s), HSREB members, and Office of Human Research Ethics (OHRE) staff.

The HSREB members are responsible for determining whether or not a research study meets the criteria for approval.

4. DEFINITIONS

See Glossary of Terms

5. SPECIFIC POLICIES AND PROCEDURES.

5.1. Minimal Criteria for Approval of Research

In order for a research study to receive HSREB approval, during its review, the HSREB takes the following into consideration:

5.1.1. The investigator has the qualifications to conduct the research;

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

5.1.3. There is a state of clinical equipoise where interventions are being compared;

5.1.4. The research will potentially 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. 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 for diagnostic or treatment purposes, whenever appropriate;

5.1.7. Risks to participants are assessed to be *reasonable* in relation to anticipated benefits, if any, and the importance of the knowledge that will be generated. In evaluating risks and benefits, the HSREB will consider those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that participants would receive even if not participating in the research). The HSREB should not consider long-range effects of applying the knowledge gained in the research;

5.1.8. Selection of participants is equitable. In making this assessment, the HSREB will take into account the purposes of the research and the research setting. The HSREB considers 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 research:

- Non-English speaking participants should not be systematically excluded because of inconvenience in translating informed consent documents,
- Participants should not be taken from one group simply because it is convenient,
- The research includes both women and men when appropriate, and does not arbitrarily exclude the participation of persons of reproductive ages;

5.1.10. When some or all of the participants are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study and in the HSREB review process to protect the rights and welfare of these participants;

5.1.11. The amount and method of payment to participants to assure there is no coercion or undue influence and that information regarding payment to participants, including method, amounts, and schedule is provided to participants as applicable;

5.1.12. Informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with and to the extent required by applicable regulations and guidelines. In certain situations, the HSREB may approve a consent procedure that does not include, or which alters (e.g. deferral), some or all of the elements of informed consent, or waive the requirement to obtain informed consent.

5.1.13. The informed consent form accurately explains the research and contains the required elements of consent;

5.1.14. The informed consent process is clearly described in the application in accordance with relevant regulations;

5.1.15. There are provisions for on-going data and safety monitoring, as evidence by a data safety monitoring plan (DSMP), that are appropriate to the size, complexity, phase, and level of risk of the study. The HSREB may recommend or require the use of a data monitoring committee (DMC) to enhance participant protection;

5.1.16. Where appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data;

5.1.17. There are adequate provisions for continued access to the agent or device, or adequate replacement, after the study is completed, when appropriate;

5.1.18. There are adequate provisions for 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. Where appropriate, as deemed by the Board, and for the purposes of reducing bias, the research study has been registered on a publicly accessible registration website and the registration number has been submitted to the HSREB prior to REB approval. When deemed to be required, registration must include the study's inclusion and exclusion criteria, outcomes to be measured, sample size, and other important study details.

5.2. **Additional Criteria**

5.2.1. Studies proposing access to or collection of personal health information require consideration of additional items to protect the privacy of the personal health 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, or children, or prisoners, or pregnant women shall be applied when applicable in accordance with governing principles and/or Regulations.

5.3. **Length of Approval Period**

5.3.1. The HSREB shall review research studies appropriate to the degree of risk, but not less than once a year;

5.3.2. The HSREB may require review more often than annually when there is a high degree of risk to participants relative to the population,

5.3.3. The HSREB may consider review of research more often than annually when there is a high degree of risk to participants relative to the population. Some examples include, but are not limited to:

- The proposed procedures have not been used before in humans,
- The stage of the research is such that many of the risks are unknown,
- More than minimal risk exists to vulnerable populations with no or minimal prospect of direct benefit,
- There have been previously confirmed instances of serious or continuing non-compliance with the applicant Principal Investigator,
- The HSREB believes that more frequent review is required.

6. REFERENCES

6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2);
6.2. The International Conference on Harmonization Guidelines for Good Clinical Practice, Sections 3, 4.1, 4.8;
6.3. Ontario's Personal Health Information Protection Act (PHIPA);
6.4. Personal Health Information Protection and Electronic Documents Act (PIPEDA);
6.5. Canadian Institutes for Health Research (CIHR) Best Practices for Protecting Privacy in Health Research (September 2005);
6.6. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.111;
6.7. ISO 14155 Clinical investigation of medical devices for human subjects – Good Clinical Practice.

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyy
404.001	Original	01/20/2014
404.002	Updated Erika Basile position Added section 5.1.18 Revised section 5.3.2 for clarification Minor administrative changes for clarity	05/22/2014
404.003	Minor administrative corrections for clarity	05/10/2016
404.004	Administrative corrections for clarity	01/27/2022