TITLE	**403: Initial Review – Criteria for HREB Approval**
SCOPE	All health research submitted to the Health Research Ethics Board (HREB) operating under the direct authority of the Health Research Ethics Authority (HREA)
APPROVAL AUTHORITY	Ethics Director
EFFECTIVE DATE	April 2024

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 HREB, independent of the review pathway (i.e., Full Board or Delegated review).

2.0 DEFINITIONS

See the Glossary of Terms.

3.0 RESPONSIBILITIES

HREB members and Research Ethics Office (REO) Personnel are responsible for ensuring that the requirements of this SOP are met.

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

4.0 PROCEDURE

All research involving human participants will meet certain criteria before HREB approval will be granted. The criteria are based on the guiding ethical principles of the Tri-Council Policy Statement 2 (2022) and are specified below. HREB approval of research is based on assessment of a complete submission to the HREB. The HREB and/or REO Personnel will consult the Researcher for additional information as necessary.

In addition to HREB approval, the requirements of the organization where the research will be conducted must also be met before the research may begin (e.g. department approvals, adequate resources).

4.1 Minimal Criteria for Approval of Research

The following criteria will be met, as applicable, in order for research to receive HREB approval:

1. The Researcher will have the qualifications to conduct the research.

2. Any potential conflicts of interest will be declared and managed appropriately to prevent any compromises to the safety or well-being of the participants or to the integrity of the data.

3. There will be a state of clinical equipoise when there is a comparison of two or more treatment arms.

4. The research will generate knowledge that could be generalized and lead to improvements in health or wellbeing.

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

6. Where applicable, the risks to participants will be minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk and by using procedures already being performed on the subjects for diagnostic or treatment purposes.

7. The selection of participants will be equitable. In making this assessment, the HREB will take into account the purpose of the research and the research setting. The HREB will consider the scientific and ethical reasons for including vulnerable populations, if applicable.

8. There will be sound scientific and ethical reasons for excluding classes of persons who might benefit from the research.

9. Additional safeguards will be included in the research and in the REB review process to protect the rights and welfare of the participants when some or all of the participants, are either children, prisoners, the elderly, pregnant women, those with mental health issues, and those with diminished capacity for self-determination who may be vulnerable to coercion or undue influence, in the context of research.

10. Recruitment methods respecting the privacy of individual participants will be followed.

11. The amount and method of payment to participants will be appropriate to ensure that there is no undue influence and that information regarding payment to participants including method, amounts and schedule is provided to participants when applicable.

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 appropriate local, provincial or national guidelines or regulations.

13. The informed consent form will accurately explain the research and contain the required elements of consent.

14. The informed consent process will be appropriately documented in accordance with the relevant local, provincial and federal regulations.

15. Any waiver of the informed consent process will be properly justified; any alteration of the informed consent process will be properly justified and documented.

16. Where applicable, 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 HREB may recommend the use of a Data and Safety Monitoring Board (DSMB) to enhance participant protection.

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

18. Where applicable, 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.

19. There will be adequate provisions for the timely publication and dissemination of the research results.

20. The resources required for successful completion of the study will be committed (e.g., funding, space, personnel).

21. If applicable, evidence that the research has been or will be registered via an internationally recognized clinical trial registry will be required.

4.2 Additional Criteria

4.2.1 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, including but not limited to the *Personal Health Information Act*.

4.2.2 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 as described in TCPS2 shall be applied when applicable in accordance with governing principles and/or Regulations. Researchers are advised to consult with the appropriate Aboriginal Research Advisory Committee (RAC) prior to conducting research with a particular Indigenous community or on Indigenous lands. Approval from the applicable RAC is required before HREB approval will be granted.

4.3 Length of Approval Period

4.3.1 The HREB shall review research at periods appropriate to the degree of risk and at least annually.

4.3.2 The HREB may require review more often than annually where there is a high degree of risk to participants relative to the population or as required by the continuing review procedure.

4.3.3 In instances where the research project has been continually renewed and modified over several years, the HREB may request a new application be submitted.

5.0 REFERENCES

Health Research Ethics Authority Act: An act to establish a health research ethics authority for the province. (2011). Retrieved from: SNL2006 CHAPTER H-1.2 - HEALTH RESEARCH ETHICS AUTHORITY ACT (assembly.nl.ca)

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans: https://ethics.gc.ca/eng/documents/tcps2-2022-en.pdf

U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46): Part 46. PROTECTION OF HUMAN SUBJECTS (govregs.com)

International Conference on Harmonization – Good Clinical Practice (ICH-GCP 4.1.1): ICH GCP - 4. INVESTIGATOR - ICH GCP

U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.111 (a)(3)): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.111