TITLE	**102: Activities Requiring HREB Review**
SCOPE	The activities of 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 specific research activities that require HREB review, and conversely, those activities that do not require HREB review.

2.0 DEFINITIONS

See 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.

4.0 PROCEDURE

All health research involving human participants must be reviewed and approved by the HREB, before the research may begin. Determination of exemption from HREB review must be based on legislative and regulatory guidelines and relevant organizational and/or institutional criteria. This determination will be made by the HREB.

4.1 Research Requiring HREB Review

4.1.1 The following requires ethics review and approval by the HREB before the research commences:

- health research involving living human participants; and
- health research involving human biological materials (as well as human embryos, fetuses, fetal tissue, human reproductive materials and stem cells). This applies to materials derived from living and deceased individuals.

4.2. Research Exempt from HREB Review

4.2.1 Research that relies exclusively on publicly available information does not require HREB review when:

- the information is legally accessible to the public and appropriately protected by law; or
- the information is publicly accessible and there is no reasonable expectation of privacy.

4.2.2 HREB review is not required for research involving the observation of people in public places where:

- it does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups;
- individuals or groups targeted for observation have no reasonable expectation of privacy; and
- any dissemination of research results does not allow identification of specific individuals.

4.2.3 HREB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information. Activities whose primary goal is to generate knowledge in relation to human health, health care and health care systems, and involving human beings as research subjects, health care information respecting human beings and human biological material, require HREB review.

4.2.4 The opinion of the HREB must be sought whenever there is any doubt about the applicability of the guidelines and regulations to a particular research project.

4.3 Activities Not Requiring HREB Review

4.3.1 Activities outside the scope of research subject to HREB review may still raise ethical issues that would benefit from careful consideration by an individual or a body capable of providing some independent guidance, other than the HREB.

4.3.2 Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this SOP, and do not fall within the scope of HREB review.

4.3.2.1 Where data are collected for purposes set out in section 4.3.2, but later proposed to be used for research purposes, such use may be considered secondary use of information not originally intended for research, which would require research ethics review.

4.3.3 Creative practice activities, in and of themselves, do not require HREB review. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to HREB review.

5.0 REFERENCES

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 2.2-2.6: https://ethics.gc.ca/eng/documents/tcps2-2022-en.pdf

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)