SOP 004_02

Title	Research Requiring REB Review
SOP Code	SOP 004_02
Effective Date	30-June-2023

Site Approval/Authorization to Adopt

Name and Title of Local Personnel (Type or print)	**Signature**	**Date dd/Mon/yyyy**
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1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to describe research activities that require Research Ethics Board (REB) review, those that are exempt from review, and activities that are not defined as research requiring review.

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

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

4.0 PROCEDURE

All research involving human participants must be reviewed and approved by an REB prior to commencement of activities. No recruitment of or interaction with human participants in research may begin until an REB has reviewed and approved the ethics application and respective documents.

4.1 Research that Requires REB Review

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

(a) Research involving living human participants,

(b) Research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

4.2 Research Exempt from REB Review

4.2.1 Research that relies exclusively on publicly available information does not require

REB review when:

(a) The information is legally accessible to the public and appropriately protected by law,

(b) The information is publicly accessible and there is no reasonable expectation of privacy;

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

(a) It does not involve any intervention staged by the Researcher, or direct interaction with the individuals or groups,

(b) Individuals or groups targeted for observation have no reasonable expectation of privacy, and
(c) Any dissemination of research results does not allow identification of specific individuals;

4.2.3 REB 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;

4.2.4 The opinion of the REB should be sought whenever there is any doubt about the applicability of the guidelines and regulations.

4.3 Activities Not Requiring REB Review

4.3.1 Activities outside the scope of research requiring REB 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 an REB;

4.3.2 Quality assurance and quality improvement studies, program evaluation activities, 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 REB review;

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

5.0 REFERENCES

Health Canada, Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects, (Schedule 1024), June 20, 2001.

Health Canada, Guidance for Industry, Good Clinical Practice: Consolidated Guideline, ICH Topic E6, 1997.

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2014.

Department of Justice (Canada), Personal Information Protection and Electronic Documents Act (PIPEDA), updated 2006.

Pharmaceutical Inspection Convention, Pharmaceutical Inspection Co-operation Scheme, Annexe 11, Computerised Systems.

US Food and Drug Administration, Code of Federal Regulations, Title 21, Volume 1:

- Part 11, Electronic Records; Electronic Signatures, (21CFR11).
- Part 50, Protection of Human Subjects, (21CFR50).
- Part 54, Financial Disclosure by Clinical Investigators, (21CFR54).
- Part 56, Institutional Review Boards, (21CFR56).
- Part 312, Investigational New Drug Application (21CFR312).
- Part 314, Applications for FDA Approval to Market a New Drug (21CFR314).

US Department of Health and Human Services, Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects (45CFR46).