

Title	Research Requiring REB Review
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Table of Content

1 Purpose..... 1

2 Scope 2

3 Responsibilities..... 2

4 Definitions 2

5 Procedures..... 2

 5.1 Research that Requires REB Review 2

 5.2 Research Exempt from REB Review 2

 5.3 Activities Not Requiring REB Review..... 3

6 References 3

7 Revision History 4

8 Appendices 4

1 PURPOSE

The purpose of this standard operating procedure (SOP) is to describe research activities that require Research Ethics Board (REB) review and research activities that do not.

2 SCOPE

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

3 RESPONSIBILITIES

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

4 DEFINITIONS

See Glossary of Terms.

5 PROCEDURES

All research involving human participants must be reviewed and approved by an REB. No intervention or interaction with human participants in research, including recruitment, may begin until an REB has reviewed and approved the research protocol, consent documents, and recruitment materials.

5.1 Research that Requires REB Review

5.1.1 The following requires ethics review and approval by an REB before the research commences¹:

- Research involving human participants and/or personal data,
- 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.

5.2 Research Exempt from REB Review

5.2.1 Research that relies exclusively on publicly available information does not require REB review if either of the following conditions applies²:

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

¹ 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, hereafter "TCPS2", art. 2.1. See also: *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique, Gouvernement du Québec, Ministère de la Santé et des Services sociaux*, June 1998, hereafter "PAM", p. 11.

² TCPS2, art. 2.2.

5.2.2 REB review is not required for research involving the observation of people in public places where all the following conditions apply³:

- The research 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:
 - (a) 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 Biological materials collected as part of health care are never anonymous;
 - (b) The opinion of the REB can be sought whenever there is any doubt about the applicability of the guidelines and regulations to a given research study.⁵

5.3 Activities Not Requiring REB Review

5.3.1 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 review⁶;

5.3.2 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 subject to REB review⁷;

The initial exploratory phase during which researchers may contact individuals or groups to develop research partnerships or gather information for the development of a research project does not require REB review.⁸

6 REFERENCES

See footnotes.

³ TCPS2, art. 2.3.

⁴ TCPS2, art. 2.4.

⁵ TCPS2, p. 15.

⁶ TCPS2, art. 2.5.

⁷ TCPS2, art. 2.6.

⁸ EPTC2, art. 6.11.

7 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
REB-SOP 102.001	2020-03-20	Original version

8 APPENDICES