



SOP Title	Research Exempt from HSREB Review
Number.Version	401.004
Effective Date	January 27, 2022

Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Research Ethics and Compliance		26 Jan 2022
Dr. Philip Jones Chair, Health Sciences Research Ethics Board		27 Jan 2022

1. PURPOSE

This standard operating procedure (SOP) describes the process for determining if research should be reviewed by a sanctioned university research ethics board (REB) or if it is exempt from this review process.

2. GENERAL POLICY STATEMENT

Any research involving human participants, including secondary data, and human biological materials that is conducted by any Faculty, employee, student of Western University, or Adjunct Faculty member of any department or school, regardless of where the research is carried out, must be reviewed and approved by a university sanctioned research ethics board before the research can begin.

Undergraduate and graduate courses that require or permit the students to participate in research projects as part of their training or for the purposes of assessments must have the research project reviewed and approved before the course begins .

Some studies are exempt from research ethics review as outlined below, if there is a doubt whether or not a particular research project requires ethics review, the opinion of the Director, Ethics Officer, Chair, or Vice Chair(s) should be sought.

3. RESPONSIBILITY

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

The HSREB Chair, designee, or OHRE staff member is responsible for determining whether or not a research project requires approval or can be exempt from the approval process.

4. DEFINITIONS

See Glossary of Terms

5. SPECIFIC POLICIES AND PROCEDURES.

5.1. Research Exempt from Research Ethics Approval

- 5.1.1. Research that relies exclusively on publicly available information does not require REB review when:
- 5.1.1.1. (a) the information is legally accessible to the public and appropriately protected by law; or
 - 5.1.1.2. (b) the information is publicly accessible and there is no reasonable expectation of privacy.
- 5.1.2. Research involving the observation of people in public places where:
- 5.1.2.1. (a) it does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups;
 - 5.1.2.2. (b) individuals or groups targeted for observation have no reasonable expectation of privacy; and
 - 5.1.2.3. (c) any dissemination of research results does not allow identification of specific individuals.
- 5.1.3. 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.
- 5.1.4. Quality assurance and quality improvement (QA/QI) 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 Policy, and do not fall within the scope of REB review.
- 5.1.5. 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 review.

5.2. Documentation

- 5.2.1. The REB does not usually issue exemption letters. Investigators are required to complete the appropriate forms within the online review system (e.g., QA/QI/PE form). Based on the information provided by the Investigator, if the project is determined to not be research, a letter confirming this will be issued for the Investigator to retain for their records. If the project is determined to be research, formal REB review and approval will be required before any study related activities can begin.

6. REFERENCES

- 6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) Article 2.2-2.6;

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
401.001	Original	05/26/2014
401.002	Administrative changes for clarification	07/29/2014
401.003	Minor administrative corrections for clarity	05/10/2016
401.004	Minor Administrative Changes 5.2.1 updated to reflect process	01/27/2022