|  |  |
| --- | --- |
| **Title** | Research Requiring REB Review |
| **SOP Code** | REB-SOP 102-002 |
| **N2/CAREB SOP CODE** | SOP 102-003 |
| **Effective Date** | YYYY-MM-DD |

|  |  |  |
| --- | --- | --- |
| **Status** | **Name and Title** | **Date** |
| ***Author of Harmonized Template*** | REB SOPs developed by CATALIS Network | 2023-05-01 |
| ***Approved*** | REB Full Board Meeting, XXX | YYYY-MM-DD |
| ***[Approved] or [Acknowledge receipt]*** | CA, XXX | YYYY-MM-DD |

**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 4

6 References 4

7 Revision History 4

8 Appendices 4

# 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.

# Scope

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

# Responsibilities

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

# Definitions

See Glossary of Terms.

# Procedures

All research involving human participants must be reviewed and approved by an REB.[[1]](#footnote-1) 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.

## Research that Requires REB Review

### The following requires ethics review and approval by an REB before the research commences[[2]](#footnote-2):

* Research involving human participants and/or personal data conducted under the auspices of the institution,[[3]](#footnote-3)
* Research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells, conducted under the auspices of the institution.[[4]](#footnote-4) This applies to materials derived from living and deceased individuals.

## Research Exempt from REB Review

### Research that relies exclusively on publicly available information does not require REB review if either of the following conditions applies[[5]](#footnote-5):

* 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;

### REB review is not required for research involving the observation of people in public places where all the following conditions apply[[6]](#footnote-6):

* 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:

5.2.3 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.[[7]](#footnote-7) Biological materials collected as part of health care are never anonymous.[[8]](#footnote-8)

1. REB review is not required for research that relies exclusively on the re-use of de-identified human somatic cell lines where:[[9]](#footnote-9)
* the researcher will comply with known consent terms;
* the researcher does not know or have access to the identity of the participant;
* the researcher will not take any steps to identify the participant; and
* the research is unlikely to reveal the identity of the participant.
1. REB review is not required for research that relies exclusively on the re-use of identified human somatic cell lines where:[[10]](#footnote-10)
* the cell line is already available and identified in the public domain;
* it is impossible or impracticable to seek participant consent;
* the researcher will comply with known consent terms; and
* the research is unlikely to harm the participant.
1. 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.[[11]](#footnote-11)

## Activities Not Requiring REB Review

### 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[[12]](#footnote-12);

### 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[[13]](#footnote-13);

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. [[14]](#footnote-14)

# References

See footnotes.

# Revision History

|  |  |  |
| --- | --- | --- |
| **SOP Code** | **Effective Date** | **Summary of Changes** |
| REB-SOP 102-001 | 2019-04-01 | Original version |
| REB-SOP 102-002 | YYYY-MM-DD | Updated in line with regulations in effectUpdated references |
|  |  |  |

# Appendices

1. REB-SOP 101-002, art. 5.1.1. [↑](#footnote-ref-1)
2. 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 2018, hereafter “TCPS2”, art. 2.1. See also: *Cadre de référence ministériel pour la recherche avec des participants humains, Gouvernement du Québec, Ministère de la Santé et des Services sociaux*, October 2020, hereafter “*Cadre*”, art. 1.5. [↑](#footnote-ref-2)
3. REB-SOP 101-002, art. 5.1.1. [↑](#footnote-ref-3)
4. REB-SOP 101-002, art, 5.1.1. [↑](#footnote-ref-4)
5. TCPS2, art. 2.2. [↑](#footnote-ref-5)
6. TCPS2, art. 2.3. [↑](#footnote-ref-6)
7. TCPS2, art. 2.4.; TCPS2, Application under art. 2.4 “Anonymous information and human biological materials are distinct from those that have been coded, and also from those that have been anonymized.” [↑](#footnote-ref-7)
8. In the view of REB members of the CATALIS advisory committee, the paragraph is compliant with art. 22 of the Civil Code of Québec*.* [↑](#footnote-ref-8)
9. TCPS2, art. 12.21. [↑](#footnote-ref-9)
10. TCPS2, art. 12.22. [↑](#footnote-ref-10)
11. TCPS2, Application under art. 2.4; TCPS2, Application under art. 12.21; TCPS2, Application under art. 12.22; *Cadre*, art. 1.5. [↑](#footnote-ref-11)
12. TCPS2, art. 2.5; *Cadre*, art. 1.5. [↑](#footnote-ref-12)
13. TCPS2, art. 2.6. [↑](#footnote-ref-13)
14. TCPS2, art. 6.11. [↑](#footnote-ref-14)