

SOP	Process for Non-Research Activities Exempt from REB Review
This policy pertains to:	All quality improvement, quality assurance and program evaluations submitted to the UBC PHC REB
Responsibility for executing this policy:	REB Administrative Staff [REBA]
Approval authority:	Director, Clinical Research Administration
Effective date:	April 8, 2025

1. PURPOSE

The purpose of this Standard Operating Procedure is to describe the process for activities that do not require Research Ethics Board (REB) review including the following types of projects:

- Quality Assurance studies
- Quality Improvement studies
- Program evaluation activities

Non-research activities do not require REB review even if they employ methods and techniques similar to those in research (Articles 2.5 and 2.6). The above activities are exempt from the requirement for REB review in accordance with both UBC Policy LR9 and the Tri-Council Policy Statement 2: Ethical Conduct for Research involving Humans, Article 2.5

Link to Article 2.5 of the Tri-Council Policy Statement (2022)

https://ethics.gc.ca/eng/tcps2-eptc2 2022 chapter2-chapitre2.html

2. SCOPE

This SOP pertains to the PHC REB and the Research Ethics Board Administration (REBA) office

3. RESPONSIBLITIES

All REB members, REBA Office Personnel and Providence Research Investigators are responsible for ensuring that the requirements of this SOP are met

4. PROCEDURE

4.1 Investigators who are not certain whether their project requires REB review (and have not yet completed an on RISe)

To determine whether a study qualifies as Quality Assurance/Quality Improvement or Program Evaluation, researchers should refer to the ARECCI (Alberta Research Ethics Community Consensus Initiative) guidelines and screening tool. The ARECCI Screening tool helps to determine the level of risk of a given project, the types of ethical risks and the appropriate types of ethics review.

https://arecci.albertainnovates.ca/

The ARECCI tool should be completed prior to contacting the REB office. Investigators must respond "No" to the 3 "Preliminary Questions" to proceed to the critical questions.

If the tool identifies the study as exempt, the Investigator should proceed to Article 4.3 below. If the researcher has any doubt regarding the decision provided by the ARECCI tool, please proceed per the paragraph below.

If the ARECCI score is inconclusive and/or advises that the REB be consulted, the Investigator must email the REB Manager (<u>Alex Trethewey</u>) to request an assessment by the REB Chair and/or Associate Chair. Investigators must include in this request:

Documentation of ARECCI completion

- Study summary/abstract
- Protocol/Project Summary (if available)

The Chairs may have additional questions or comments prior to issuing their decision. Investigators must respond to these upon request.

The decision by the Chair(s) will be communicated back to the investigators by REBA staff via email.

If the Chair and/or Associate Chair identifies the study as exempt, the Investigator should proceed per Article 4.4 below

4.2 Investigators who have submitted an exempt application on RISe:

In the event a non-research application has been submitted, the application will be assigned to the Chair(s) who will review/confirm that the activity is exempt from the requirement for ethics review. They may require that the Investigators complete the ARECCI tool as part of their determination and/or that further details be provided. REBA staff will contact the researcher by email to make these requests. If the project is determined to be exempt from REB review, the application will be returned to the Investigator on RISe with instructions for how to permanently delete the application from the system. The Researcher must then proceed per 4.3 below.

4.3 Consultation with the Information Access and Privacy Office (IAPO)

Activities outside of the scope of research subject to REB review may still raise ethical issues that would benefit from careful consideration by an individual or body capable of providing some independent guidance other than the REB. In PHC, that body is the Information Access and Privacy Office (IAPO).

Once confirmed that the project is outside the REB's purview, Investigators must take the following steps:

Complete the VCH-PHC Quality Improvement Intake form found at: VCH PHC Quality Improvement Intake Form Submit the completed form to privacy@providencehealth.bc.ca for any projects taking place within Providence Health Care

4.4 Letter of Acknowledgement

It is understood that publication is some journals may require REB acknowledgement. In these cases, a Letter of Acknowledgement can be provided from the REB upon request of the Investigator. This letter will confirm that the REB has deemed the study exempt from the requirements for REB review/approval, in accordance with both UBC Policy LR9 and the provisions of the Tri-Council Policy Statement 2: Ethical Conduct for Research involving Humans, Article 2.5).

Issuance of a QA/QI acknowledgement from the REB does not preclude publication of the completed study. Researchers are encouraged to consult with any known preferred publications in advance to determine their requirements

5. PROCEDURE EVALUATION

To ensure appropriate oversight of this new Standard Operating Procedure (SOP), it should be reviewed by the REB Manager and the Chair and Associate Chair at six months post-implementation. This review will take place via a report prepared by the REB Manager to the Chair and Associate Chairs indicating how the SOP is working and any challenges that arise related to the SOP. The review will be repeated at one year post-implementation if deemed necessary by the Chair/Associate Chairs and/or REB Manager.

6. REFERENCES

Link to UBC Policy LR9

https://universitycounsel.ubc.ca/files/2022/05/Human-Research-Policy LR9.pdf

Link to Article 2.5 of the Tri-Council Policy Statement (2022) https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter2-chapitre2.html

PHC Evaluation, Data, Analytics, Quality Improvement, and Research

Difference between evaluation, data analytics, quality improvement, and research.pdf