

GUIDANCE NOTES ON REQUESTING FHREB EXEMPTION LETTERS

INTRODUCTION

This guidance note is intended to provide information on what types of activities are exempt from FHREB review and how and when to request an FHREB exemption letter.

GUIDANCE NOTE #1: DEFINITION OF RESEARCH

The [Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans \(TCPS 2, 2018\)](#) defines research as:

An undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation.

All research under Fraser Health auspices or jurisdiction, as defined by the [Fraser Health Research Policy](#), which involves human participants (including the secondary use of data or records about human participants, e.g., medical records) or human biological materials requires FHREB review and approval prior to commencement.

GUIDANCE NOTE #2: EXEMPT ACTIVITIES

In accordance with Article 2.5 of the TCPS 2:

Quality assurance and quality improvement 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.

The intention to publish does not in itself determine whether a project qualifies as research requiring REB review, rather than quality improvement or program evaluation. Similarly, data collection methodologies such as surveys, focus groups, and interviews are not exclusive to research. The determination of exemption is made based on the project purpose/objective.

Other exempt activities include:

- Creative practice activities that are not intended to elicit data that will be analyzed to answer a research question
- Public health surveillance work conducted in fulfillment of Fraser Health's business mandate
- Research that relies exclusively on information that is publically available through a mechanism set out by legislation or regulation and that is protected by law
- Research that relies exclusively on information that is in the public domain and the individuals to whom the information refers have no reasonable expectation of privacy
- Research that relies exclusively on the observation of people in public places* where:

- It 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
- Research that relies exclusively on secondary use of anonymous information so long as the process of data linkage or recording or dissemination of results does not generate identifiable information
- Medical case reports in which the number of subjects is less than three

***Fraser Health hospital and clinic sites, including lobbies, waiting areas, and cafeterias, do not qualify as public spaces. Any observational research activities occurring in these spaces require FHREB review and approval.**

The authority for the determination of exempt activities rests exclusively with the FHREB. However, the FHREB does not provide oversight, guidance, or consent form templates for projects that do not qualify as research involving humans.

GUIDANCE NOTE #3: WHEN IS AN EXEMPTION LETTER REQUIRED

While the FHREB is the authority for the determination of exempt activities, it is neither required nor expected that exemption letters will be sought for most projects. Exemption letters may be requested for the following reasons:

- Exempt research in which a research cost-centre from Fraser Health is required
- Quality improvement, program evaluation, or other exempt activities in which there is an intention to publish the results and such a letter is required by the journal editor
- Uncertainty by the project team as to whether the project qualifies for exemption

GUIDANCE NOTE #4: REQUIREMENTS FOR REQUESTING AN EXEMPTION LETTER

In order to request an exemption letter from the FHREB, please submit the following information to REB@fraserhealth.ca:

1. Completed Research vs. QI/Program Evaluation Checklist
2. A project summary or description which clearly states the PURPOSE/OBJECTIVE of the project.

The FHREB will review the submission and make a determination of exemption. Exemption letters are provided by the FHREB as a courtesy, and turnaround times vary in accordance with

the current FHREB workload. Research ethics submissions will take priority over exemption letter requests.

It is neither necessary nor encouraged to submit an FHREB Initial Submission Application Form when requesting an exemption letter. Project descriptions should clearly indicate the project is not research (e.g., avoid terms such as “research objectives” and “research question”, etc.), unless the request is being made because there is genuine uncertainty whether the project qualifies as research requiring FHREB review.

Exemption letter requests must be made prior to the initiation of the project, without exception. For projects in which an exemption letter has been issued by the FHREB, the project team is responsible for all other required project approvals, including the Data Access Agreement submission to the Fraser Health Office of Information Privacy, where applicable.

The FHREB does not provide any oversight or services for projects qualifying for an exemption. Fraser Health employees or privileged physicians conducting quality improvement or program evaluation activities may wish to contact the following departments for additional services:

1. [Fraser Health Office of Information Privacy](#) for non-research survey templates and requirements and data access agreements
2. [Physician Quality Improvement](#) for quality improvement training and resources. Please email PhysicianQI@fraserhealth.ca for more information.
3. The [Department of Evaluation and Research Services](#) for development of project plans, logic models, evaluation plans, surveys, as well as assistance with data analysis and dissemination.