**Research vs. Quality Improvement/Program Evaluation Checklist**

The purpose of this document is to assist Fraser Health employees and privileged physicians in determining whether their project fits under the category of research requiring Fraser Health Research Ethics Board (FHREB) approval, or if it is a quality improvement/program evaluation activity exempt from review.

In accordance with the [**Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2018)**](http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf), research is defined as:

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

Projects at Fraser Health that qualify as research are subject to all Fraser Health research-related policies, and must have FHREB approval as well as a Letter of Authorization from the Department of Evaluation and Research Services prior to commencement.

Quality improvement and program evaluation projects are generally exempt from FHREB review when conducted exclusively for internal business purposes. However, it can be difficult at times to determine whether a project is research or quality improvement/program evaluation. This checklist can be used to provide an initial assessment of whether FHREB review is required.

**CHECKLIST**

Project Title: Click here to enter text.

Project Lead: Click here to enter text.

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| **ANSWER ALL QUESTIONS IN THIS SECTION** | **YES** | **NO** |
| Does your project involve the use of a pharmaceutical drug, device, or natural health product which requires Health Canada approval? |[ ] [ ]
| Is the projected funded by, or being submitted to a research funding agency for a grant or award that requires research ethics review? |[ ] [ ]
| Is this a quality improvement or program evaluation project where the data will also be used for an explicit research purpose? |[ ] [ ]
| **If YES to any of the above, submit for FHREB review** |

If “No” to all, please complete the following sections.

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| **CHECK ALL THAT APPLY**  | **YES** | **No** |
| **Primary aim of the project** | Establish generalizable facts/principles/theories/concepts/knowledge |[ ] [ ]
|  | Describe a phenomena that is not well understood in the scientific or medical community |[ ] [ ]
|  | Establish effect of an intervention/medication that has not been previously tested or results of previous tests are not conclusive |[ ] [ ]
|  | Answer a research question |[ ] [ ]
|  | Test a hypothesis |[ ] [ ]
|  | Improve a program/process/system |[ ] [ ]
|  | Measure sustained improvement and measurement is ongoing |[ ] [ ]
|  | Evaluate or implement a practice/service |[ ] [ ]
|  | Improve performance as judged by accepted/established standards |[ ] [ ]
| **Review** | Independent peer review has been conducted on the protocol |[ ] [ ]
|  | No independent peer review has been conducted on the protocol |[ ] [ ]
| **Design** | Follows a research design leading to scientifically valid findings |[ ] [ ]
|  | Includes a robust literature review and identifies a gap in this literature that will be addressed by the research question |[ ] [ ]
|  | Involves randomization of participants |[ ] [ ]
|  | Uncertainty whether intervention is advantageous to the participants |[ ] [ ]
|  | Control for variables or confounders to promote generalizability of the results |[ ] [ ]
|  | Uses quality improvement methods (e.g., Plan-Do-Study-Act cycle) aimed at producing change within the organization |[ ] [ ]
|  | A comprehensive review of literature has not been done |[ ] [ ]
|  | The intervention is specific to the needs of the participants where the project takes place |[ ] [ ]
| **Risk** | May place participants at risk, or the risks are not well understood in the literature |[ ] [ ]
|  | Does not expose participants to any risk  |[ ] [ ]
| **Audience** | Primacy audience for the findings is external (e.g., scientific community) |[ ] [ ]
|  | Is the project funded by an outside organization with a commercial interest in the use of the data and/or results?  |[ ] [ ]
|  | Primary audience for findings is internal or local |[ ] [ ]
| **If YES any questions in BLUE, the project is most likely research requiring FHREB review** |

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| **FOR STUDENT/RESIDENT PROJECTS, COMPLETE THIS SECTION** | **YES** | **NO** |
| Is this project conducted in fulfilment of a paper or thesis in which original research is required?  |[ ] [ ]
| Is this project fulfilling a business mandate of Fraser Health, but record-level data (e.g., patient charts) will be secondarily used and analyzed for a final report/paper/thesis? |[ ] [ ]
| Is this project evaluating a process/program/service delivery or change in Fraser Health, and the student will collect data for a secondary objective that fulfills a research question?  |[ ] [ ]
| Is this project conducted in fulfilment of a pedagogical or class requirement to learn/practice data collection techniques (e.g., surveys, focus groups, etc.)? |[ ] [ ]
| Is this project fulfilling a business mandate of Fraser Health using data that is not normally publically available, and results will be reported in a final report/paper? |[ ] [ ]
| Is this a chart review in which the study results will be generalizable to a wider population?  |[ ] [ ]
| Is this a chart review addressing a site-specific issue, and results will only be relevant to the site where the review was conducted? |[ ] [ ]
| Is this project fulfilling a business mandate of Fraser Health, and data will remain in Fraser Health custody and only information that is publically available will be reported in a final report/paper? |[ ] [ ]
| Is the delivery or implementation and evaluation of a process/program/service delivery or change the principal aim of the project (rather than a final report/paper)? |[ ] [ ]
| Is this project evaluating a process/program/service delivery or change in Fraser Health and would occur regardless of the student’s involvement, and no research question is being answered in the final report/paper? |[ ] [ ]
| **If YES any questions in BLUE, the project is most likely research requiring FHREB review** |