**RESEARCH ETHICS BOARD - EXEMPTION**

**GUIDANCE DOCUMENT & CHECKLIST**

**BACKGROUND AND PURPOSE**

In some cases, it can be difficult to determine if a project is an actual research study or if it is a quality improvement project.

TCPS2 states *“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 and do not fall within the scope of REB review.”*

This guidance document and checklist are tools to assist research staff to determine whether their project falls under the category of research or quality improvement. It is important to note that studies that appear to be predominately quality improvement may have elements that deem them a research study.

**HOW DO I APPLY FOR AN EXEMPTION?**

* Review the table below to compare the characteristics of clinical research and quality improvement projects.
* Complete each item listed in the checklist.
* Submit the completed checklist along with a **one page summary** of the project to the REB for review by the Research Ethics Coordinator and the REB Chair. The final authority as to whether a project requires REB approval lies with the REB Chair/Vice-Chairs.
* The REB will issue the final determination in a letter to the researcher/research team for their records.

***Note: this process applies to research staff (including investigators outside the institution), fellows, residents, volunteers and students.***

**IF THIS IS QI, CAN I STILL PUBLISH?**

QI initiatives are often conducted in the vein of learning. It is important to share and replicate QI successes through various channels. This may include presentations at meetings and publications in journals. The intent to publish QI findings does not mean that the project must be REB reviewed. The publication must make it clear that it is the result of a QI initiative.

Prior to the start of a project, the REB will issue a letter if a project is deemed to be Quality Improvement that will indicate the project is exempt from REB review. Journals may request evidence of REB exemption if you wish to publish. This review process may be included in the methodology section of your paper and/or the checklist may be submitted to the journal for review.

**Note: *The REB will not retroactively review projects that have already been completed.***

**KEEP IN MIND!**

As a project changes over the course of time, a QI project may morph into a project that would be considered research. Each time your project changes, please refer to this checklist and reassess the need for REB review/approval. If you are uncertain, submit to the REB for assessment.

**RESEARCH & QUALITY IMPROVEMENT PROJECT CHARACTERISTICS**

|  |  |  |
| --- | --- | --- |
|  | **Clinical Research** | **Quality Improvement** |
| **Purpose** | A systematic investigation to establish facts, principles or contribute to generalizable knowledge. | To implement knowledge, evaluate or improve a process or program through established/accepted standards. |
| **Design** | Follows a rigid protocol that remains unchanged. | Adaptive, iterative design. |
| **Mandate** | Activities not mandated by the institution. | Activities are mandated by institution as part of operations. |
| **Starting Point** | Knowledge seeking is independent of routine care and intended to answer a question or test a hypothesis with the intention of contributing to generalizable knowledge. | Knowledge seeking is integral to ongoing management system(s) for delivering health care. |
| **Population** | Usually involves a subset of individuals and a specific sample size. | Includes information on all affected by process or program change. |
| **Benefits** | May or may not benefit current participants; intent is to benefit future patients. | Immediately and directly benefits a process, system, or program; may or may not benefit patients. |
| **Risks** | May put participants at risk with consent. | No increased risk to patients with exception of possible patients’ privacy or confidentiality of data. |
| **Data Collection Strategy** | Systematic data guided. | Systematic data guided. |
| **Testing or Analysis** | Statistically prove or disprove a hypothesis. | Compare program, process or system to established standards. |
| **Effect on Program or Practice** | Findings of these studies are not generally expected to have an immediate affect or change practice. | Findings of study are expected to directly and immediately affect institutional/program practice. |
| **Adoption of Results** | Dissemination of results may require more time. | Dissemination of results occurs rapidly and is adopted into local care delivery. |
| **Endpoint** | Answer a research question and/or invite critical appraisal of that conclusion by peers through presentation. | Improve a program, process or system. |
| **Publication/Presentation** | Intent to publish is generally presumed at the onset of the project. | Intent to publish may or may not be presumed at the onset of the project but QI practitioners are encouraged to share systematic reporting of insights. |

**CHECKLIST ASSESSMENT PROCESS**

Complete Section “A”

“Yes” to ***any*** question

Complete Section “B”

“No” to all questions OR “yes” to only a few questions

“No” to all questions

“Yes” to most questions

Submit checklist & summary to REB

for assessment

REB application is required

“Yes” to at least one of the questions

**QUALITY IMPROVEMENT OR RESEARCH DETERMINATION CHECKLIST**

**PROJECT TITLE:** Click here to enter text.

|  |  |  |
| --- | --- | --- |
| **Section “A”** | **Yes** | **No** |
| Project will develop or test the efficacy of a new intervention that has not been studied before, or test hypothesis about issues that are beyond the knowledge of current science. |  |  |
| Establish or test clinical practice standards where none are already in place. |  |  |
| Prospective Assignment of patients/providers into different procedures or therapies (such as randomization). |  |  |
| A control group for whom the procedure or therapy or study intervention is withheld to allow an assessment of its efficacy. |  |  |
| Caregivers will be “blinded” to an element of care. |  |  |
| Prospective evaluation of a drug, procedure or device not currently approved by Health Canada. |  |  |
| Explore a previously unknown phenomenon with a marketed or approved product (i.e. off label use of a drug, device or natural health product). |  |  |
| National or provincial registry or database from which a hypothesis will be tested. |  |  |
| **Funding:**  Is the project funded by an entity (a sponsor or granting agency) that makes clear its mission to conduct research, or has a commercial interest in the results of the activity or are funds being requested from the institution to support this activity? |  |  |
| **Consent:**  Will the activity require voluntary informed consent for interventions that are not part of standard clinical care? |  |  |
| **Risk:**  Is the risk to the participants separate from what is involved in the care they are receiving? |  |  |
| **Publication:**  Is the primary purpose of the project to produce results for publication in a ***research*** journal? |  |  |

**I have selected “yes” to one or more of the items above?**

**Yes** – *please complete an ethics application for review*

**No** – *please continue with the checklist to determine if this project requires REB review.*

|  |  |  |
| --- | --- | --- |
| **Section “B”** | **Yes** | **No** |
| **Project Purpose:**   1. Is the project intended **primarily** to develop a better practice within your organization or program? 2. Is the project intended to be part of an ongoing process of gathering or monitoring data within your organization or program? |  |  |

***Please submit the completed checklist and your project summary to the REB for review.***

Is your project initiated from, or involved in, a clinical program at The Royal?

**Yes  No**

**Investigator’s Declaration:**

I confirm that the information answered above is a true and accurate reflection of my project.

If the project is determined to be research, I will submit an application to the REB for review & approval.

For projects deemed to be QI, I will retain the letter of exemption issued by the REB, and will reassess the project as changes occur to ensure it remains a QI initiative.

Name: Click here to enter text.

Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: Click here to enter a date.