BCIT Research Ethics Board

Is my project exempt from ethics review?

Not all projects need REB review. Follow the instructions in this document to determine whether:

1. your project is exempt, and

2. if your project is exempt, whether you will need to apply for a letter of exemption

**Authority of the Research Ethics Board**

“All research projects involving human participants, undertaken by members of the BCIT community—including all administrators, faculty, staff and students, including students carrying out research as part of class assignments and institutional research—fall within the jurisdiction of the BCIT Research Ethics Board (REB). The BCIT REB’s jurisdiction applies, irrespective of the source of financial support (if any), or the project location, as long as the investigator represents the work as BCIT research. Projects conducted by researchers from outside the BCIT community who access Institute resources (equipment, personnel, or participants), may also fall within the jurisdiction of the BCIT REB.” [BCIT Policy 6500]

**Ethical Research**

“Research involving human participants is premised on a fundamental commitment to advancing human welfare, knowledge, and understanding, and to examining cultural dynamics. Researchers undertake or fund research involving human participants for many reasons. An ethic of research involving human participants should include two essential components:

1. The selection and achievement of acceptable ends

2. The acceptable means to those ends

The first component is directed at defining acceptable ends in terms of the benefits of research for participants, for associated groups, and for the advancement of knowledge. The second component is directed at ethically appropriate means of conducting research” [BCIT Policy 6500]

The REB will use the TCPS2 to evaluate research projects. Some projects, however, don’t actually qualify as research for the purposes of REB review.

**A – Is my project exempt from REB review?**

There are two kinds of exemptions from REB review.

1. In some cases, you may not have to submit your project for evaluation to the REB (so you don’t need to prepare an application of any kind)
2. In other cases, even though your project will not be reviewed for ethics compliance, you still need to submit a request to get a letter with confirmation of exemption

First, you will need to determine **whether the project is likely exempt from REB review.** Check any appropriate boxes. You will likely need to read the relevant definitions (see links) to make sure.

1. **Publicly available information** when: the information is **legally accessible** to the public and appropriately protected by law; **or** the information is publicly accessible and there is **no reasonable expectation of privacy** (see [here](http://www.ger.ethique.gc.ca/eng/tcps2-eptc2_2018_chapter2-chapitre2.html)).[ ]
2. **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 (see [here](http://www.ger.ethique.gc.ca/eng/tcps2-eptc2_2018_chapter2-chapitre2.html)).[ ]
3. **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 (see [here](http://www.ger.ethique.gc.ca/eng/tcps2-eptc2_2018_chapter2-chapitre2.html)).[ ]
4. **Quality assurance and quality improvement studies**, program evaluation activities and performance reviews, or testing within normal education requirements (see [here](http://www.ger.ethique.gc.ca/eng/tcps2-eptc2_2018_chapter2-chapitre2.html)).
	* If you’re considering exemption under this category, fill out the **BCIT REB Research Checklist** (further down this document)
	* What did you get on the checklist? The project is most likely exempt if: not a single YES in Part I AND not a single NO in Part II [ ]

**B- It’s clear that my project is exempt. Is a formal request for exemption necessary?**

If you have checked at least one the above boxes 1-3 and therefore determined the project is exempt from REB review according to the TCPS2, you are done. You don’t have to apply for REB review.

If your project is exempt under category 4, the **BCIT REB Research Checklist** will tell whether you may still need to submit to the REB a request for exemption. This is much simpler than applying for ethics review.

**C - My project is NOT exempt and needs to be reviewed by the REB, or I’m not sure. What do I do?**

1. If you are not sure, contact the REB chair and include this filled out document, and, if applicable, the **BCIT REB Research Checklist** (fill out the checklist only if you are considering exemption regarding category 4) along with the 1-page summary that is asked there. Explain why you are not sure
2. If you do know the project requires REB review, you will need to prepare an application. You don’t need to submit this document or the **BCIT REB Research Checklist.**
3. **If you are a Forensics or Environmental Health student**, you need to prepare a pre-review process with your instructor, and only after this step will your application be ready to submit to the REB. Contact your instructor for more details. The pre-review package is available from the REB web site.

**BCIT REB Research Checklist**

**Determining Whether a Project is Research or Quality Improvement,**

**Quality Assurance, Program Evaluation, or**

 **Curriculum Development**

Projects at BCIT that qualify as research must be reviewed and approved by the BCIT REB. Under the Tri-Council Policy Statement 2 (TCPS 2), research is defined as:

…an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation. The term “disciplined inquiry” refers to an inquiry that is conducted with the expectation that the method, results, and conclusions will be able to withstand the scrutiny of the relevant research community.

However, we’ve seen the TCPS 2 specifically exempts some types of projects from REB review under 4 categories. This section of the document deals specifically with exemption category 4:

**Quality assurance and quality improvement studies, program evaluation activities and performance reviews, or testing within normal education requirements [curriculum development or evaluation], when used exclusively for assessment, management or improvement purposes** (see [here](http://www.ger.ethique.gc.ca/eng/tcps2-eptc2_2018_chapter2-chapitre2.html)).

**Is my project exempt of ethical review?**

Note that BCIT REB has the final authority to determine whether a project qualifies for exemption as QI, QA, or program evaluation. If you are uncertain whether your project is exempt for any of the reasons mentioned above, and/or after completing the checklist below, do contact the REB, mentioning why it may be exempt, and why you suspect it might not be.

**If my project is exempt, may I still need an exemption letter confirming this?**

Generally, if your project is exempt, you don’t need to apply for an exemption letter.

In some cases, however, you don’t need to apply for *review*, but you may still need to apply to the REB to get an **exemption letter** stating that your application doesn’t need a review. If your project does qualify as QI/QA or program evaluation based on the TCPS, but **you later wish to publish your findings**, journals will often ask for a letter from the REB that the project was exempt from review. Therefore, if publication or presentation is a possibility, apply to the REB for an exemption letter even if your project is determined to be QI/QA. This is a much simpler process than applying for a review.

Please note that the REB only issues exemption letters **prior** to the initiation of a project, and not after its completion.

If your project is exempt based on the TCPS2 AND you need confirmation from the REB that it is exempt please submit:

* A summary of your project (no more than 1 page, please)

If you need proof that it’s exempt *as QI/QA*, please ALSO submit the following to the REB:

* The checklist below

**How do I determine whether my project is QI or Research?**

That is the purpose of this document and the checklist below.

QI/QA and program evaluation initiatives are systematic, data-guided activities designed to bring about immediate improvements in health care or other service delivery in particular settings. Research studies are intended to create new knowledge that can be generalized to other populations and settings.

Although intentions can be mixed, it is the **primary** intent of the developers of the project that determines whether a project is research or QI/QA. Is the primary intention to create knowledge for the benefit of the broad scientific or scholarly community (research), or does the project intend primarily to benefit the local institution and the people it serves (QI/QA or evaluation)?

Please see the Table and the Checklist below to help determine the appropriate status of the project. Depending on your answers, you may be done after you finish the checklist (you don’t need to submit anything unless you need an exemption letter) or you may need to contact the REB.

|  |
| --- |
|  **Characteristics of Research and Quality Improvement Projects** |
|  | **Research** | **Quality Improvement/Assessment** |
| **Definition** | A systematic investigation to establish facts, principles or generalizable knowledge that involves human participants, including patient data and biological materials. | An activity where the primary purpose is to monitor, evaluate or improve the quality of services delivered by an individual or organization. |
| **Intent of Project** | To answer a question, or test a hypothesis with the intention of contributing to generalizable knowledge. | Intent of project is to improve a practice or process within a particular institution, or specified group of institutions, or ensure it conforms to expected norms. |
| **Design** | Designed to develop or contribute to generalizable knowledge; may involve randomization of individuals to different treatments, regimens, or processes; or novel research ideas supported by literature search. | Not designed primarily to develop or contribute to generalizable knowledge; generally does not involve randomization to different practices or processes. |
| **Mandate** | Activities generally not specifically mandated by the institution or program. | Activities mandated by the institution or clinic as part of its operations. |
| **Population** | Usually involves a subset of individuals and specific sample size. Universal participation is not expected; generally, statistical justification for sample size is used to ensure significant endpoints can be met. | Information on all or most receiving a particular treatment or undergoing a particular practice or process expected to be included; exclusion of information from some individuals may significantly affect conclusions. |
| **Effect on Program or Practice** | Findings of the study are generally not expected to directly or immediately affect institutional or programmatic practice. | Findings of the study are expected to directly affect institutional practice and identify corrective action(s) needed. |
| **Benefits** | Participants may or may not benefit directly. A benefit, if any, to individuals may be incidental or delayed. | Participants continuing to use tested services are expected to benefit directly from changes or refinements to the services. |
| **Adoption of Results** | Dissemination of results may require more time. | Dissemination of results may occur rapidly and are intended to be adopted into institutional program(s). |
| **End Point** | Answer a research question, and/or invite critical appraisal of that conclusion by peers through presentation. | Improve a program, process, or service; implement, monitor and sustain program improvement. |
| **Publication/****Presentation** | Intent to publish or present is generally presumed at the outset of project as part of professional expectations, and/or obligations; and usually occurs in research/scientific publications, grant proposals, or other research/scientific forum. Results are expected to contribute to generalizable knowledge by filling a gap in scientific knowledge or supporting, refining, or refuting results from other research studies. | Intent to publish or present generally not presumed at the outset; dissemination of information often does not occur beyond the institution evaluated. It may occur in quality improvement publications/fora. When published/presented to a wider audience, the intent is to suggest effective models, strategies, assessment tools or provide benchmarks or base rates rather than to develop or contribute to generalizable knowledge. |

**CHECKLIST**

|  |  |
| --- | --- |
| **Project Title:** |  |
| **Project Lead:** |  | **Date:** |

**Part 1 – “Yes” answers tend to indicate Research and not QI/QA**

|  |  |  |
| --- | --- | --- |
| 1. Is the project/study being presented to the public, colleagues, the institution, your department or others (including students) as a “research” project: that is, do you consider the project research?
 | **Yes**[ ]  | **No**[ ]  |
| 1. Is the project funded by (or being submitted to) a grant/award competition from a funding agency that requires research ethics review?
 | **Yes**[ ]  | **No**[ ]  |
| 1. Does the project involve randomization to compare interventions with participants, or use other sampling techniques to divide participants into different groups?
 | **Yes**[ ]  | **No**[ ]  |
| 1. Does it involve a control group for whom the procedure or therapy or study intervention is withheld to allow an assessment of its efficacy?
 | **Yes**[ ]  | **No**[ ]  |
| 1. Does the project intend either to test a novel intervention, drug, device, treatment or program, or test hypotheses about issues that are of broad interest, or beyond the knowledge of current science?
 | **Yes**[ ]  | **No**[ ]  |
| 1. Does your project involve a prospective evaluation of drug, procedure or device not currently approved by Health Canada?
 | **Yes**[ ]  | **No**[ ]  |
| 1. Is your project exploring a previously unknown phenomenon with a marketed or approved product (i.e. off-label use of a drug/device)?
 | **Yes**[ ]  | **No**[ ]  |
| 1. Is the project design and methodology rigorous enough to support statistical generalizations beyond the particular population that will participate in the project?
 | **Yes**[ ]  | **No**[ ]  |
| 1. Will your project be blinding caregivers to any element of care?
 | **Yes**[ ]  | **No**[ ]  |
| 1. Is there a national or provincial registry/database from which a hypothesis will be tested?
 | **Yes**[ ]  | **No**[ ]  |
| 1. Is the project designed to support generalizations that go beyond the particular population the sample is being drawn from?
 | **Yes**[ ]  | **No**[ ]  |
| 1. Is the **primary** purpose of the project to produce the kind of results that could be published in a research journal?
 | **Yes**[ ]  | **No**[ ]  |

 **Part 2 – “No” answers tend to indicate Research and not QI/QA**

|  |  |  |
| --- | --- | --- |
| 1. Is the project intended **primarily** to develop a better practice within your organization or setting?
 | **Yes**[ ]  | **No**[ ]  |
| 1. Is the current project part of a continuous process of gathering or monitoring data within an organization?
 | **Yes**[ ]  | **No**[ ]  |
| 1. Would this project still be done at your site even if the results might not be applicable anywhere else?
 | **Yes**[ ]  | **No**[ ]  |

**I’ve completed the checklist. What’s my next step?**

* If the answer to any of the questions in Part 1 is **yes,** or the answer to any of the questions in Part 2 is **no,** then the study/project may still not be research but **a determination of this by the REB is required.** Please contact the BCIT Research Ethics Board to clarify this. You may be told your project is exempt or you may be asked to prepare an application for ethics review.
* Otherwise STOP HERE. You are done. You don’t need to submit anything to the REB.