



a place of mind

THE UNIVERSITY OF BRITISH COLUMBIA

Checklist for quality improvement/quality assurance/program evaluation/curriculum development studies requiring ethical review

Many organizations use a variety of systematic methods to improve their functioning and performance. These activities may take the form of quality assurance and quality improvement studies, program evaluation activities and performance reviews, or testing within normal education requirements. These activities are within the mandate of such organizations and are generally administered in the ordinary course of their operations.

Under the Tri Council Policy Statement on *Ethical Conduct for Research Involving Humans*, studies conducted for such purposes are distinguished from research requiring REB review. According to Articles 2.1 and 2.5 of the TCPS:

Research is “an undertaking intended to extend knowledge through disciplined inquiry or systematic investigation”, whereas **quality assurance and improvement studies**, “when used exclusively for assessment, management or improvement purposes, do not constitute research”.

Although QA/QI activities often look research-like, and may contain methods used in research studies (e.g. surveys, interviews, etc.), because the purpose of such activities differs from the intent of research, they are outside the scope of REB review. Although QA/QI studies may raise ethical issues that benefit careful consideration by the project team, the consent procedures for such studies generally depart from those required for research.

However, where one of the goals of such QA/QI activities is to “extend knowledge”, they may fall under the TCPS definition of research and therefore require review.

As there is a high degree of uncertainty about where the line between research and QA/QI should be drawn, the following checklist provides an aid to help researchers determine whether their study requires ethics review.

Please note that an intent to publish your findings is not the litmus test for whether your study should be reviewed by the Behavioural Research Ethics Board.

Most journals ask for details of ethical approval or a statement that it was not required. If you wish to publish the results of a genuine QA/QI study, you would simply explain that under Article 2.5 of the Tri Council Policy Statement, QA/QI activities are not subject to institutional ethical review.

Does your project warrant review by the Behavioural Research Ethics Board?

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 <input type="checkbox"/> No <input type="checkbox"/>
2.	Is the project funded by (or being submitted to) a grant/award competition from a funding agency that requires research ethics review?	Yes <input type="checkbox"/> No <input type="checkbox"/>
3.	Does the project involve “randomization” to contrast interventions to participants or other systematic sampling techniques to divide participants into different groups?	Yes <input type="checkbox"/> No <input type="checkbox"/>
4.	Does the project involve a comparison of interventions or processes and “control” settings or groups either to test a new intervention or to assess the effectiveness of a process change?	Yes <input type="checkbox"/> No <input type="checkbox"/>
5.	Does the project involve pilot testing or evaluation of a new intervention, treatment or program, for which it would be difficult to estimate a balance of risk and benefit in advance?	Yes <input type="checkbox"/> No <input type="checkbox"/>
6.	Is the project design and methodology rigorous enough to statistically support generalizations beyond the particular population that will participate in the project?	Yes <input type="checkbox"/> No <input type="checkbox"/>

If the answer to any of the above questions is “yes” an application to the appropriate Research ethics Board should be made. The study/project may not be research but a determination of this by the REB is required.