

Applying to the UBC BCCA Research Ethics Board: Characteristics of a project that the REB looks for, whether it is 'quality assurance' or 'research'.

The UBC BCCA Research Ethics Board reviews projects submitted to it that fulfill [criteria for 'research'](#). From time to time, BCCA staff or faculty members will engage in projects designed primarily to improve the system or evaluate the performance of individuals or the system by reviewing administrative or clinical processes, patterns of care or patient outcomes. Evaluation projects that are intended mainly to generate information for internal systems improvement, rather than as generalizable knowledge are usually classified as "quality assurance" (QA).

QA projects, unlike formal research projects, do not require REB approval, but the REB is prepared to provide letters of acknowledgement where necessary (e.g., peer review journals) if a project leader decides subsequently to submit a QA project for publication that was not originally reviewed by the REB, if the journal requires such a letter, *as long as there is adequate prospective documentation* of the processes used. The REB thus encourages all evaluation projects (including QA) to be conducted under the guidance of a *pre-written* protocol.

The REB discourages applications for REB approval of QA projects solely for the purpose of future publication. **If, however, there is uncertainty about whether the project is QA or research requiring ethics approval, it would be prudent to submit to the REB for review because the REB cannot provide retrospective ethics approval for a research project.**

If an applicant is submitting a project to the REB for approval, whether it is considered by the applicant to be QA or formal research that requires ethics approval, the REB will review the quality of the methodology used to carry out the project because methodological quality is one of the key elements of ethical research. The principle of proportionality will be followed, which balances expectations for scientific rigour against risks to participants.

In general, the REB looks for the following characteristics of any project submitted to it for review/ approval:

- There is a clearly stated study question(s) or formal hypothesis;
- The study architecture or evaluation design is appropriate to answering the questions posed or testing the stated hypotheses;
- The methods used to answer the question(s) or test the hypotheses are rigorous, within practical constraints, and the methods address issues to minimize bias, ensure that proper conclusions or inferences can be made, and address issues of feasibility including sample size. The REB will apply the *principle of proportionality*;
- If the study is quantitative, the statistical approach is appropriate and justified. There is a clear link between the question being addressed, the methods used to address them, and the statistical approaches used. Where studies are exploratory, the statistical approaches may be descriptive only;
- If a study is described as a feasibility or pilot study only, there should be clear justification of the reason why this is a pilot, and how the results of this study will be used;
- If the study is mainly qualitative in nature, the rigor of the methods used and the analytic procedures is reviewed. This includes survey-type research, which can involve quantitative as well as qualitative elements;
- The REB reviewer will look for a clear statement as to how the results of the study are intended to be used. For example, if an applicant performs a retrospective study of patient outcomes for different treatments or over different time periods, the REB would caution against the results as sufficient to influence future clinical policy, unless a compelling justification is made. Similarly, the REB will generally not favorably look upon changes in clinical policy based on either retrospective or prospective cohort studies that do not include a concurrent control, or where a study is labeled by the PI as either 'feasibility' or a 'pilot';
- For all studies, the REB reviewer will be alert to the following: appropriate strategies for ensuring subject safety, ensuring subject autonomy (avoiding all manner of coercion whether blatant or subtle), informed consent, and fair subject selection where appropriate, data handling & access, privacy protection, and issues of potential conflicts of interest.

While the REB looks at these issues for all applications submitted to it, of course we encourage all studies whether classified as research or QA to be as rigorously designed and carried out as possible, whether or not submitted to the REB.

These guidelines are not intended to be comprehensive, but attempt to provide some sense of what an applicant should expect when making a decision about submitting a study to the REB and whether or not to label it as QA or research.

Vancouver Coastal Health and Providence Health Care have together developed a "**VCH/PHC QI & REB review checklist**" to help researchers distinguish between QA and research studies, which is located on the VCH webpage: <http://www.vchri.ca/s/Home.asp>

For further insights into approaches for classifying studies as QA or formal research, you may consult the following link:

[http://www.ahfmr.ca/arecci/pdf/ARECCI%20Ethics%20Guidelines%20FINAL\(ISBN\)%20Aug%2025%2008.pdf](http://www.ahfmr.ca/arecci/pdf/ARECCI%20Ethics%20Guidelines%20FINAL(ISBN)%20Aug%2025%2008.pdf)