

# Is This Research? A Case of Ethical Tensions in Evaluating Canadian Experiential Education in Pharmacy

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## BACKGROUND

In 2014, the Association of Faculties of Pharmacy of Canada (AFPC) undertook a project to investigate and implement a national approach to experiential education (ExEd) in Canadian Pharmacy programs. Project aims include:

- \* *the current state of ExEd in pharmacy in Canada;*
- \* *best practices for delivering ExEd; and*
- \* *prototypes for achieving best practices on a national scale*

Data collection for the project employs methods from qualitative research, including literature review and semi-structured key informant interviews. Thematic and mixed inductive/deductive data analysis approaches have been similarly informed by qualitative research methodologies.

At an early stage in the project, the question arose: **Should this work be formally conceived of as research, or rather as a form of program evaluation or quality improvement?** A resolution was important in determining the necessity of a rigorous and time-consuming process of securing research ethics board (REB) approval from one or more of the involved universities.

## METHODS

The determination of whether to secure formal ethics approval from a university research and ethics board (REB) ultimately hinges on the determination that a project constitutes research – and not quality improvement (QI): the former requires ethics approval, whereas the latter does not [1].

The research team met and formulated a series of sub-questions to help resolve our broader concern around appropriately defining the project:

1. **What differentiates research from quality improvement (QI) projects?**
2. **Can the findings of QI projects be published, and under what conditions?**
3. **To what degree should QI projects incorporate ethical standards?**

In order to answer these time-sensitive questions, several sources were consulted:

- \* *project stakeholders;*
- \* *a university REB;*
- \* *a Canadian government policy statement on research ethics; and*
- \* *a developing body of scholarly and institutional literature pertaining to the differences between research and QI.*

## RESULTS

### What differentiates research from quality improvement (QI) projects?

The data collection methods used in both research and QI can be similar, and the lines between the two can at times be blurred for this reason, particularly when qualitative approaches are used [2-4]. Unlike research, however, QI does not attempt to produce generalizable knowledge, answer a broad question, or engage in hypothesis testing. Instead, QI projects aim to evaluate and ultimately improve existing systems or programs within a local context [5, 6].

### Can the findings of QI projects be published?

Although publication of results in peer-reviewed journals is not typically a primary aim of QI projects, and some such journals require documentation of REB approvals, the dissemination of QI findings through presentations at scholarly meetings and publications in various journals can be appropriate [5]. When QI data are shared in posters or publications, it must be made explicit that 'learnings were gleaned not through research (for wider application) but through a quality improvement/quality assurance project carried out in a local context.[7]' However, if data are initially collected within a QI framework, but are later proposed for dissemination as 'research', REB review may be required [1].

### Should QI projects incorporate ethical standards?

Some authors characterize the 'scant ethical attention' typically received by quality improvement projects as a concern, suggesting that ethical standards should be upheld by such projects regardless of their exemption from formal REB approval [2, 8]. Canada's Tri-Council Policy Statement on the Ethical Conduct of Research Involving Humans is explicit in this regard (article 2.4):

*"Activities outside the scope of research... may still raise ethical issues that would benefit from careful consideration... by an individual or a body capable of providing some independent guidance, other than an REB [1]."*

## DISCUSSION

It was clear that the AFPC project was employing multiple data collection and analytic methods from qualitative research to evaluate the current state of pharmacy experiential education in Canada. Although dissemination of project findings was ultimately a secondary aim, **the primary purpose of the project was program evaluation:** a form of QI. Furthermore, despite many project stakeholders holding faculty positions at universities, **the project itself was initiated by a non-university organization (AFPC).** As such, **it was determined that no university-based REB approval process would be undertaken.**

However, **ethical standards** informed by university REB guidelines **have been incorporated across the project.** For example, an **informed consent process** was undertaken with key informants being interviewed, and informants' anonymity will be largely preserved when reporting project learnings. In addition, all associated **publications make clear that project learnings were procured through a QI process** rather than through research. However, because the project includes a considerable literature review component in addition to key informant interviews and document review, it is conceivable that published learnings may be 'generalizable' outside of the Canadian pharmacy context, demonstrating the **nebulous boundaries between research and QI.**

We **recommend** that others in similar situations **consider consulting with their university REB** in determining whether their projects are research or QI; and that **projects determined to be QI, independently incorporate rigorous ethical protocols where possible.**

## CONCLUSION

This case study highlights the **complex considerations and blurred lines between research and program evaluation/quality improvement:** an issue increasingly negotiated by researchers and project managers and associated university REBs. Despite the determination that the current project is not formal 'research' per se, ethical practices such as informed consent and protected confidentiality, which are common in formal academic research, have continued to play an important role alongside 'qualitative research'-based data collection and analysis. This account may prove informative for others undertaking similar evaluative projects.

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