

Review of: "Quality improvement and research differences: A guide for DNP and PhD faculty"

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Potential competing interests: No potential competing interests to declare.

Thank you for the invitation to review this manuscript. It provides an interesting perspective which should be of value to the research community.

General comments

Agree with another reviewer who suggested eliminating the pronoun "we." Also suggest eliminating the pronouns "you/your," for example, in the sentence "*However, the determination of whether your project constitutes a quality improvement project versus a human subjects research study...*" suggest replacing the word "your" with "a"

Agree with another reviewer who suggested this manuscript has applicability beyond nursing, suggest including a statement(s) to that effect in the manuscript Introduction

Specific comments

Not sure if the current Title clearly describes the essence of the manuscript, which seems to be why consider an IRB submission for QI research. Perhaps use a title like: "Quality improvement in a research context and why an Institutional Review Board submission may be important"

Suggest including in the opening paragraph information on why QI in healthcare and why it is becoming more important—i.e. across care settings CMS is driving a shift toward value-based health care/quality measurement reporting and clinicians are therefore becoming more involved in QI and taking on more QI projects/roles

For the sentence "*In this manuscript, the distinction between QI and human subjects research will be examined with the goal of explaining the differences between the two and dispelling misconceptions regarding QI*" seems like a stronger ending is needed, to explain what examining these differences will ultimately do. Is the manuscript trying to improve the quality of QI research and help graduate students/faculty realize that it is usually prudent to seek IRB review for QI research? If this is the overall goal of the manuscript (and it seems to be) suggest including it here, and then summarizing the sections that will be presented in the manuscript to support this recommendation (i.e. provide an overall roadmap of the arguments that will be presented to reach this conclusion)

Also, since this sentence is defining the goal of the manuscript, seems that the next several paragraphs are a different

section. Maybe the next few paragraphs should be labeled “Introduction”?

The sentence “*Scholarship is defined as, “... the generation, synthesis, translation, application, and dissemination of knowledge that aims to improve health and transform health care. (p. 2).”* seems to be a definition of nursing scholarship specifically, not scholarship in general. Thus, suggest inserting the word “nursing,” i.e. “*Nursing scholarship is defined as, ...*”

The Introduction would benefit from some type of Figure to show the interrelationships of the concepts presented—this could help the reader better follow the logic flow.

The statements “*Most certainly quality improvement projects are not human subjects research as formulated by those authoring Title 45 CFR §46. However, this does not pertain to the methodology used in quality improvement projects, only the conceptualization of how quality improvement is to be conducted*” could benefit from a bit more explanation

The phrase “*initiative is a human subjects research or is a quality improvement project*” seems to be missing something, maybe include the word “study” after the word “research”?

Table 4 provides examples of QI and research stand-alone projects as well as QI projects that become research. Suggest using the terms “human subjects research stand-alone projects” vs. just “research” since this manuscript specifically focuses on human subjects research

Regarding the “*Does multi-faceted fall prevention intervention (e.g., eLearning module, in-situ simulation, and introduction of falls champions) increase unit nurses’ fall prevention knowledge and behaviors?*” study, if this study in some way tests/reports nurses’ knowledge and behaviors, then couldn’t it potentially be interpreted as human subjects research, because results from nurses are being reported? Also, why is there no information in the Characteristics column for this multi-faceted fall prevention intervention study?

In addition, it looks like example “c” is missing from table 4. Is example “c” the “human subjects research” example?

Regarding the statement “*In the early 21st century, the science of quality improvement came of age*” why did it come of age? Suggest providing some further explanation.

The information included in “*The Ethics of Quality Improvement Projects*” is interesting, but needs a transition from the previous paragraph so the reader can follow why the information is included at this particular point in the manuscript.

The opening paragraph of the section “*To IRB or not to IRB, that is the Question*” would also benefit from some type of transitional sentence from the previous section.

The statement “*In the final analysis, it is the (federal) Office of Human Research Protection (OHRP) that will make the determination of research or QI*” seems to imply that IRB requests routinely go to the OHRP, suggest rewriting this

sentence to clarify.

The sentence “*In light of these potentially severe consequences, the literature suggests a more narrow view of not seeking IRB approval for quality improvement projects may be ethically feasible*” is awkward and difficult to understand—suggest rewriting this sentence.

In the paragraph with the sentence “*It is the responsibility of the clinician to obtain informed consent from potential project subjects*” would it be appropriate to state that if the research study has an informed consent, then the researcher should always reach out to an IRB?

The statements “*So why bother with the IRB review for quality improvement projects, given they can be time-consuming and delay implementation? Because ethical risk to subjects and professional risk to the investigators is too high to forego review. Further, most venues for formal dissemination of data will require an IRB review whether through academic publication or conference presentation. Most IRBs maintain an expedited review process for minimal risk and presumed exempted status*” are key points, but come late in the manuscript. If ultimately the recommendation is that even if a research project is deemed QI, “human subjects research” should be viewed in a broader context and thus it is suggested/encouraged that researchers seek IRB approval, then suggest stating this concept much sooner in the manuscript. Perhaps this means reordering the manuscript a bit to first provide the recommendation and then lay out the evidence of why this recommendation is being made.