Research Article

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

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Misconceptions regarding quality improvement (QI) projects and their role within the human subjects research paradigm exist. Projects resulting in information applicable to local institutions with an emphasis on dissemination of the process implemented represent QI projects. Studies resulting in generalizable knowledge represent human subjects research. The chief misconception is that projects using experimental and quasi-experimental designs are not QI. Defining QI based on methodology is incorrect. Determination of whether a study is or is not QI lies in the study's purpose. Nineteen study designs applicable to QI are presented. To assist faculty in determining whether a proposed study is considered human subjects research or QI, several tools are presented, and the IRB process in the context of QI is discussed. To ensure the rigor of QI, the SQUIRE guidelines are reviewed to provide guidance to faculty project directors. Finally, best practices for QI ethical considerations and human subjects research are emphasized.

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We know nurses make a difference in patient care because we have evidence of nurses making a difference in many sustentative ways within the healthcare paradigm (Kutney-Lee et al., 2015; Petit Dit Dariel & Regnaux, 2015; Saunders & Vehvilinen-Julkunen, 2016; Stone et al., 2019). The Magnet Recognition Program (MRP) has established goals that promote quality, identify excellence in nursing care, and disseminate best practices (American Nurses Credentialing Center, n.d.). There is evidence the MRP is responsible for achieving better organization, and increased patient and staff outcomes while reducing healthcare costs through quality improvement and human subjects research (Wolf et al., 2014).

From the perspective of a statistician, peer reviewers, and nursing faculty, we have noticed misinformation regarding the methodology of quality improvement projects. Graduate nursing students may perceive that methodology defines a quality improvement project, whereas it should be defined by the scope of the scholarly activity. The misunderstanding stems from how quality improvement (QI) fits within the broader context of scholarly activity and the human subjects research paradigm. In this manuscript, the distinction between QI and

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human subjects research will be examined with the goal of explaining the differences between the two and dispelling misconceptions regarding QI.

Scholarship is defined as, "... the generation, synthesis, translation, application, and dissemination of knowledge that aims to improve health and transform health care. (p. 2)." (American Association of Colleges of Nurses, 2018). The *Oxford Learner's Dictionary* defines research as, "a careful study of a subject, especially in order to discover new facts or information about it" (Deuter et al., 2020). Melnyk & Fineout-Overholt (2019) describe that the purpose of quality improvement projects is to identify and fix processes leading to an internal problem within the clinical setting, whereas the purpose of human subjects research is to generate new knowledge/external evidence (p. 42). Thus, scholarly nursing practice is characterized by both discovery and application of new discoveries in increasingly complex practice situations.

We can look to Boyer's model of scholarship and the element of application which involves using research findings and innovations to remedy societal problems and explain the human subjects research-QI relationship (Boyer, 1997). This is often referred to as "Scholarship of Practice". The DNP Essentials describe Scholarship of Practice as the translation of research into practice and the dissemination and integration of new knowledge (American Association of Colleges of Nursing, 2006). Further, the Scholarship of Practice extends the realm of knowledge beyond discovery and directs it towards humane ends. As such, nursing practice epitomizes the scholarship of practice through the intersection of basic sciences, human caring, and new understandings. DNP graduates engage in advanced nursing practice and provide leadership for evidence-based practice. This requires competence in knowledge application activities such as: translation of research in practice, evaluation of practice, improvement of reliability of practice and outcomes, and participation in collaborative research – in short, a synthesis of quality improvement and human subjects research (DePalma & McGuire, 2005). As DNP-prepared nurses move through their careers, they are likely to form strategic and productive alliances with PhD-prepared nurse researchers, physician researchers, and other clinical researchers to form interprofessional relationships that will strengthen current best evidence and enhance methodological approaches to more fully understand the processes of nursing and interprofessional clinical practice (Gray, 2018).

Further, the link between QI and human subjects research is demonstrated in the AACN DNP Essentials as they are the standard around which faculty develop DNP curricula. DNP curricula are designed to prepare graduates to formulate and evaluate, scientifically, the needs of patients and ensure accountability for the quality of care among the patient populations (American Association of Colleges of Nursing, 2006). Thus, we take the position that quality improvement is the careful study of healthcare practices in pursuit of discovery that leads to improvement based on new facts and information. Within the context of these definitions, we pose the question; how can quality improvement *not* qualify as human subjects research?

Quality improvement projects improve healthcare functions and processes. How is finding a better way to do something not on par with discovering new facts or information about a phenomenon not human subjects research within the context of healthcare? If evidence-based programs or national guidelines are implemented, shouldn't

the outcome implementation (whether positive or negative) be disseminated for the benefit of other clinicians and ultimately patients? These outcomes should come to demonstrate an opportunity for others to learn what works and what does not work on a local, regional, or national scale. We contend, quality improvement may be conducted within the framework of human subjects research and scientific methodology, and these factors alone do not distinguish whether a study is QI or human subjects research.

Untangling Quality Improvement Projects from Human Subjects Research

The scholarly activity of the advanced practice nurse falls under the broader umbrella of implementation science, improvement science, and translational science. "Implementation Research is the scientific study of methods to promote the systematic uptake of clinical research findings and other evidence-based practices into routine practice, and hence to improve the quality (effectiveness, reliability, safety, appropriateness, equity, efficiency) of health care" (Eccles et al., 2009). In scholarly activities related to healthcare, this can mean changes in behaviors, policies, clinical guidelines, or individual practices (Peters et al., 2013).

Improvement science underscores rapid-cycle testing in order to learn about change and initiate improvement (Kline & Payne, 2020). Although similar to basic research, improvement science diverges after positing the question under investigation. Instead of hypothesis testing, an advanced practice nurse will define what is considered an improvement and continue with rapid-cycle testing guided by subject matter experts and people and processes involved (Kline & Payne, 2020; West, 2011).

QI may employ the scientific method in its search for empirical evidence of better ways to treat patients. As such, it has much in common with human subjects research since it hypothesizes how a process might be improved (Baily et al., 2006). Quality improvement has a lot in common with human subjects research because it is dependent on the same qualitative and quantitative methods used in human subjects research (Baily et al., 2006).

Given the congruent dependence of methodology shared by human subjects research and quality improvement, one cannot determine based on study design or methodology whether an investigation is situated within the quality improvement or human subjects research camp. Baily et al. (2006) emphasized this position in their seminal reference operationalizing the difference between quality improvement and human subjects research. Baily et al. (2006) differentiate quality improvement projects and human subjects research defined by the Code of Federal Register Title 45 CFR §46.102(l) as "…a systematic investigation, including [human subjects] research development, testing, and evaluation, designed to develop or contribute to *generalizable knowledge* (p. 136; emphasis added) (US Department of Health & Human Services, 2018).

Nuances many nurse educators and advanced practice nurses miss is QI projects can and do produce generalizable knowledge. The problem lies in graduate training and carries over into practice when students and advanced practice nurses are incorrectly advised that their project is not human subjects research solely based on consideration of methodology. The confusion identified in the introduction of this paper is that some clinicians are being incorrectly advised that quality improvement projects are not categorized as "human subjects research"

solely based on quality improvement design methodology. Lynn et al. (2007) suggest the confusion regarding whether quality improvement projects fall under Title 45 CFR §46 arises from interpretation differences of the phrase "...designed to develop or contribute to generalizable knowledge." Here lies the nuance many miss. Quality improvement projects, strictly speaking, are not generalizable. They are specific to the institution where the investigation is conducted. However, if quality improvement project results are interpreted to be generalizable and applicable to any other people or situations, then a quality improvement project would qualify as, or become human subjects research (Lynn et al., 2007). Additionally, if in the course of studying a quality improvement project, a clinician produces generalizable knowledge then the investigation comes to represent both a quality improvement project and a human subjects research study. Further, Lynn et al. (2007) suggest that, if quality improvement in the context of patient care is designed to improve local care and produce generalizable knowledge, the activity would qualify both as a quality improvement project and as a human subjects research study. 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 (Baily et al., 2006).

The purpose of QI is to improve the process, and it may use various frameworks such as the Plan-Do-Check-Act framework by Deming (1950) – to later evolve into Plan-Do-Study-Act, the Knowledge to Action Framework (Graham et al., 2006), Titler et al's. (2001) Iowa Model of Evidence-Based Practice to Promote Quality Care, or the ACE Star Model (Stevens, 2004). Humans subjects research may use theoretical frameworks such as the National League for Nursing/Jeffries Simulation Theory (Durham et al., 2014), Bauman's Layered Learning Model (Bauman, 2016; Bauman et al., 2017, 2014; Breitkreuz et al., 2020), or Leininger's Theory of Transcultural Nursing (Leininger, 1996). In quality improvement, the project may change based on the evaluation or re-evaluation of obtained outcomes. The sustainability of outcomes is examined over time. Direction may be changed, during the project, based on how the project is progressing; whereas in human subjects research, the study is not changed part way through the research project or based on the outcome. Hence, the determination and designation of a quality improvement project are not based on methodology, but on the purpose of the study and how generalizable the results are. If the results can only be applied locally, the project is quality improvement. If the results are generalizable to other locales, the study must be viewed as human subjects research and falls under the regulations stated in Title 45 CFR §46. Key differences between human subjects research and quality improvement projects are seen in Table 1.

Element	Human Subject Research	Quality Improvement Practice
Intent	Develop or contribute to new knowledge	Improve the delivery of clinical care within a given system
Output	Results are generalizable	Results are only relevant to a specific site under study
Investigation	Addresses a specific question	Addresses a process or system
Design	Includes assessment measures pre and post	Includes ongoing assessment measures
Timing	Limited to discrete time period	Ongoing process
Focus	Addresses gap in knowledge	Addresses gap in implementation of a process
Goal	Proof of effectiveness of an intervention	Sustained improvement in care in a specific environment
Dissemination	Publication of results to scientific community may take months or years	Focused on implementing immediate improvement in care; should be shared within the system and with other similar systems
Risk to participants	Considered to be worthwhile for the benefit to society	Little or no risk; may be at a greater risk if not participating
Setting	May be independent of site where care is routinely provided	Takes place in a localized healthcare setting; incorporates specific features of the setting
Funding	Often comes from outside the agency in which the research is taking place	Often internal and managed by people who work in that setting
Management	Often conceived, funded, and managed as discrete projects	Ongoing process of continual, self-conscious change
Method	Strictly constructed protocol is maintained throughout data collection	Protocol may require repeated modifications over time and as the desired changes engage the local structures, processes, patterns, habits, and traditions
Context	Methods seek to eliminate the context	Methods are developed based on knowledge of the context

Table 1. Differences distinguishing human subjects research from quality improvement*

* *Table reprinted from Mormer, E., & Stevans, J. (2019). Clinical quality improvement and quality improvement research. Perspectives of the ASHA Special Interest Groups, 4, 27–37. https://pubs.asha.org/doi/full/10.1044/2018_PERS-ST-2018-0003. This work is licensed under a Creative Commons Attribution-NonCommercial-NoDerivs 2.0 Generic License.*

Another difference between quality improvement projects and human subjects research is the level of evidence generated by the scholarly activity. Sackett's (1989) proposed classification forms the basis for a hierarchy of levels of evidence. This hierarchy presents in decreasing order how evidence from studies should be viewed. A modified version of Sackett's Level of Evidence is seen in Table 2.

Meta-analyses
Systematic reviews
Large RCTs with clear-cut results
Small RCTs with unclear results
Cohort and case-control studies
Historical cohort or case-control studies
Case series, studies with no controls
Expert opinion

Table 2. A modified version of Sackett's (1989)* levels of evidence.

* *Sackett, D. L. (1989). Rules of evidence and clinical recommendations on the use of antithrombotic agents. Chest, 95(2 SUPPL.), 2S-4S. https://doi.org/10.1378/chest.95.2*

Going up, Table 2 infers a higher level of evidence and more rigor in the scholarship activity. Additionally, more faith is placed in the outcomes due to the randomized controlled nature of the research, which reduces the subjectivity and controls for bias. Quality improvement projects tend to use methodology on the lower half of the table, as a generalization, and are often not as rigorous as human subjects research. However, it should be remembered that rigor is not necessarily a desirable characteristic of a quality improvement initiative. Quality improvement studies should prioritize practicality and flexibility. Since these studies are examining the real-world healthcare setting, it is not possible to control for all extraneous variables. This also allows clinicians to avoid getting "bogged down" in excessive data collection (Etchells et al., 2016; Etchells & Woodcock, 2018).

Quality Improvement Project Designs

The misconception of quality improvement not qualifying as human subjects research does not lie in methodology, but in the conceptualization. There are numerous experimental (i.e., studies where randomization is applied) and

quasi-experimental designs (i.e., studies not using randomization) employed in quality improvement. Some of these designs are listed in Table 3.

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• Cluster randomized trials* (M. Campbell et al., 2000; M. Eccles et al., 2003; Grimshaw, 2000; Grol et al., 2002; Handley et al., 2018; Itri et al., 2017; Mormer & Stevans, 2019)
• Controlled pretest-posttest or before-after studies (M. Eccles et al., 2003; Grimshaw, 2000; Handley et al., 2018; Itri et al., 2017)
• Equivalent time-series (Speroff & O'Connor, 2004; Toulany et al., 2013)
• Factorial* (Speroff & O'Connor, 2004; Toulany et al., 2013)
• Incomplete block designs* (M. Campbell et al., 2000; Grimshaw, 2000)
• Individual/single-subject randomized controlled trial* (M. Eccles et al., 2003; Mormer & Stevans, 2019; Speroff & O'Connor, 2004)
• Interrupted time series (Handley et al., 2018; Mormer & Stevans, 2019)
• Meta-analyses (Grol et al., 2002)
• Mixed methods (Mormer & Stevans, 2019)
• Multiple baseline (Speroff & O'Connor, 2004; Toulany et al., 2013)
• Observational studies (Grol et al., 2002)
• Qualitative studies (Grol et al., 2002)
• Randomized controlled trial (M. Campbell et al., 2000; Grimshaw, 2000; Itri et al., 2017; Speroff & O'Connor, 2004)
• Static-group design (Speroff & O'Connor, 2004)
• Statistical process control (Grol et al., 2002; Portela et al., 2015)
• Stepped wedge (Handley et al., 2018; Mormer & Stevans, 2019)
• Systematic reviews (Grol et al., 2002; Itri et al., 2017)

• Time-series (M. Eccles et al., 2003; Grimshaw, 2000; Itri et al., 2017; Speroff & O'Connor, 2004; Toulany et al., 2013)
• Uncontrolled pretest-posttest or before-after (M. Eccles et al., 2003; Grimshaw, 2000; Itri et al., 2017; Mormer & Stevans, 2019; Speroff & O'Connor, 2004)

Table 3. Nineteen study designs from 10 different articles discussing study designs in quality improvement projects

* *Experimental design*

Quality improvement can and often does make use of comparison or control groups, and employ randomization (Handley et al., 2018). Additionally, several of the designs in Table 3. are discussed in Campbell & Stanley's (1963) seminal book entitled *Experimental and Quasi-experimental Design*, as well as in the 4th edition of Kirk's (2013) authoritative *Experimental Design: Procedures for the Behavioral Sciences*, and Cook & Campbell's (1979) classic book *Quasi-experimentation: Design & Analysis Issues for Field Settings*. These exemplary references are frequently used to guide human subjects research projects. If the same methodology is being used to analyze both human subjects research studies and quality improvement projects, then methodology alone cannot be the defining difference.

Determining What is a Quality Improvement Project and What is a Human Subjects Research Study

Guidance for determining what constitutes a quality improvement project and what is human subjects research is available through several tools. One tool is available online from Virginia Commonwealth University and can be found here: https://perma.cc/WW42-VWWH. We include three tools as Appendix A (Quality improvement or research worksheet), Appendix B (CHOP screening checklist for quality improvement (QI) projects), and Appendix C (Gilbert and Calhoun's Research Algorithm©) to assist in determining whether a proposed initiative is a human subjects research or is a quality improvement project. However, the determination of whether your project constitutes a quality improvement project versus a human subjects research study may be irrelevant in the context of determining whether a proposal should be submitted to the Institutional Review Board (IRB). This is further discussed in a later section of this paper.

It is prudent to acknowledge that projects may start as QI and then become human-subjects research as the process morphs and a focus on generalizable results emerges. Table 4 provides examples of QI and research stand-alone projects as well as QI projects that become research.

Category	Project Purpose/Question	Characteristics
QI	For geriatric patients arriving at an emergency department triage area at a hospital in a major metropolitan area in the Northeast after a fall, does the implementation of the Quick Elderly Mortality After Trauma scale developed by Morris et al. (2020)(via the smartphone app) decrease the time to activation of the appropriate trauma level?[a]	• Implements existing evidence-based practice • Improves patient care right now • Poses "minimal risk" • Benefits catchment area, not society • Involves locally affiliated investigators • Allows for modifications during implementation • Internal funding likely • Dissemination of process noteworthy, ***not*** results
QI	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?[b]	
QI → Research	In a population of women seen in an emergency department in the Southwest, does screening all women instead of only those receiving a pelvic exam result in increased detection of *Chlamydia trachomatis*.[d]	• Implements existing evidence-based practice • Improves patient care right now • Poses more than "minimal risk" • Involves locally affiliated investigators • No modifications to protocol during implementation, except those approved by IRB amendment • External funding • Plan to **publish results** because they might be important to other emergency departments

Table 4. Examples of quality improvement projects, human subjects research, and quality improvement projects transition to human subjects research

[a] *Example graciously provided by Tracylain Evans, MS, MPH, MBA, RN, TCRN, EMT/P*

[b] *Example graciously provided by Leila Cherara, DNP, MSPSL, RN, CHSE, CNE*

[c] *Example from Oermann et al. (2011)*

[d] *Example from Doezema & Hauswald (2002)*

Toward More Rigor in Quality Improvement Projects

In the early 21st century, the science of quality improvement came of age. As the science of quality improvement projects advanced, the importance of disseminating its accomplishments increased (Ogrinc et al., 2008). At the time, the content and quality of reporting improvement in healthcare varied widely as there were no standards to apply to such endeavors (Ogrinc et al., 2008). In response to the dearth of standards or guidelines related to quality improvement projects, an interdisciplinary group was formed and created the Standards for Quality Improvement Reporting Excellence (SQUIRE Statement) (Ogrinc et al., 2008). The SQUIRE statement provides a framework for reporting novel findings regarding healthcare improvements. The guidelines are intended for reports describing organizational or system-level projects improving healthcare quality, safety, and value. The SQUIRE Statement consists of a checklist of 19 items clinicians need to consider when writing articles describing formal projects of quality improvement (Ogrinc et al., 2008). Between 2012 and 2015, the SQUIRE Statement was reexamined and revised (Ogrinc et al., 2015). The revised statements emphasize three key components of methodology for quality improvement projects: 1) the use of theoretical frameworks in planning, implementing, evaluating, and interpreting quality improvement projects; 2) the context in which the work is completed; and 3) the intervention being used (Ogrinc et al., 2015). The revised statement is intended to be more broadly applicable to methods specific to quality improvement projects recognizing the complexity and multidimensionality of such projects. The revised statement provides a mutually aggregable context in which quality improvement projects can be disseminated (Ogrinc et al., 2015).

The Ethics of Quality Improvement Projects

If working under the assumption that a quality improvement project complies with ethical requirements, Lynn et al. (2007) suggest clinicians have an ethical responsibility to conduct, and patients have an ethical responsibility to participate in, quality improvement projects. The basis for this assumption is quality improvement projects are viewed as an intrinsic part of establishing and maintaining best practices in clinical care and quality improvement projects should be a part of normal healthcare operations. Thus, both patients and clinicians share the responsibility to participate in quality improvement projects to establish and maintain best practices, so all patients receive reliable and high-quality healthcare. The ethical principles for quality improvement projects include: social or scientific value, scientific validity, inclusion of fair participant selection, reflection of a favorable risk-benefit ratio, respect for participant rights, informed consent, and the investigation be conducted under some form of

independent oversight (Emanuel et al., 2000; Lynn et al., 2007). Given that ethical principles and considerations are applicable to both quality improvement projects and human subjects research studies, like methodology, ethical principles alone cannot be used to distinguish quality improvement projects from human subjects research.

It should be noted that quality improvement projects may occur at two levels – the system or hospital level and the patient level. If non-identifiable aggregate data are used in a project to investigate a process, it is reasonable to assume informed consent will not be needed and an IRB will most likely find the project to be exempt from review. However, if a clinician is investigating the implementation of guidelines or a new process to reduce morbidity or mortality at the patient level, most certainly one must submit their project to the IRB for review and let the IRB determine the extent of the review required. This may lead to a full review, expedited review, or exemption from review.

To "IRB," or not to "IRB," that is the Question

Should quality improvement projects be subject to IRB oversight? In the final analysis, it is the (federal) Office of Human Research Protection (OHRP) that will make the determination of research or QI. In a report of "a good quality improvement project gone bad," Doezema & Hauswald (2002) describe a practice change taking the stance of a quality improvement project with their IRB determining that it did not constitute human subjects research. However, a complaint made to the OHRP ruled the practice change did constitute human subjects research despite the IRB's opinion (Doezema & Hauswald, 2002). In their examination of the issue, Doezema & Hauswald (2002) suggest that ethically there is no meaningful difference between collecting data having local implications and data that are generalizable. The distinction between a quality improvement project and a human subjects research study is thought to be problematic and "mischievous (p. 11)" with most, if not all, quality improvement projects comprising human subjects research with clinicians exercising due diligence to protect human subjects (Doezema & Hauswald, 2002).

Incorrect classification of quality improvement projects can have dire implications such as an investigation by the OHRP, an institution losing all federal funding, and possibly penalties being levied (Casarett et al., 2000). This is evident in the example given by Doezema & Hauswald (2002). 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 (National Bioethics Advisory Commission & National Bioethics Advisory Commission, 2001; Nerenz et al., 2003). A broader, more conservative view of always submitting one's proposal to the IRB for review will increase human subjects' protection and is strongly recommended. We suggest an open dialogue with the IRB prior to the submission of materials to promote efficiency and to ensure proper project or research materials and applicable process expectations are met and understood.

It is the responsibility of the clinician to obtain informed consent from potential project subjects (Amdur & Bankert, 2011). Components of informed consent include voluntariness, disclosure of pertinent information, and determination of comprehension. The informed consent document must be written clearly and concisely. The

informed consent should be in final form and clinicians should not expect the IRB to edit or revise the informed consent form (Amdur & Bankert, 2011). To be safe in terms of following and meeting federal expectations related to the projection of human subjects, particularly when your project involves patients, the study should always obtain consent. In the example above, clinicians did not obtain consent and the IRB agreed with them that informed consent was not needed, yet after the fact, the OHRP differed in its subsequent opinion. We argue that the conservative approach is the only true way to ensure the rights of human subjects are protected. Further, while we emphasize the importance of human subjects' protection first and foremost, the conservative approach also provides a level of confidence related to professional and institutional safeguarding.

The language of human subjects review in the context of the term human subjects research is often confusing to novice researchers Novices are often perplexed and unnecessarily offended when their human subjects research submission comes back from review with the designation "exempt – not (human subjects) research". This does not mean that the project does not meet the rigors of the scientific method as it relates to quantitative methodology or that the project has been deemed meritless from the perspective of qualitative methodology. Rather, an exempt not (human subjects) research status means the research protocol does not meet the federal criteria for human subjects research, nothing more. In short, this is a positive review status from the IRB that allows the project or research investigation to proceed. Many educational interventions, particularly in the realm of nursing, medical and more broadly health sciences are, in fact, exempt from federal guidelines because they do not involve any risk to the subjects and the intervention is taking place as part of an established educational program.

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.

Summary

Quality improvement projects and human subjects research studies are very similar in nature and often indistinguishable in terms of the methodology used. Established ethical guidelines offer direction for novice and expert researchers, which is applicable to both quality improvement projects and human subjects research studies. The determining factor on whether an investigation is considered a quality improvement project or human subjects research is the context in which the outcome is leveraged. If the results of a project are only applicable locally, an investigation is likely a quality improvement project. If the results of a study are generalizable beyond the confines of the investigating institution and human subjects are involved, the study represents human subjects research. The discussion in this paper assists nursing faculty and graduate students engaged in investigative activities to determine the difference between a quality improvement project and a human subjects research study. The tools presented in this paper assist nursing faculty and graduate students to determine whether the scholarship activity

they are engaged in is a quality improvement project or human subjects research. Regardless of the investigation genre, it is strongly suggested and encouraged to seek IRB approval to assure human rights protection.

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Author's Contributions

GEG conceived the paper and drafted the original version. AEF contributed substantially to the manuscript content. EBB, LP, and AEF provided critical revisions. All authors approved the final manuscript.

Competing Interests

Gregory E. Gilbert, Eric B. Bauman, Lisa Paganotti, and Ashley E. Franklin have no competing interests to declare.

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Appendix A

Quality Improvement or Research Worksheet

Quality Improvement or Research Worksheet

Rachel Nosowsky, Esq.

SEQ	Issue and Guidance	Rating
1	Are patients randomized into different intervention groups in order to enhance confidence in differences that might be obscured by nonrandom selection? *Randomization done to achieve equitable allocation of a scarce resource need not be considered and would not result in a "yes" here.*	☐ Yes ☐ No
2	Does the project seek to test issues that are beyond current science and experience, such as new treatments (*i.e.*, is there much controversy about whether the intervention will be beneficial to actual patients – or is it designed simply to move existing evidence into practice?). *If the project is performed to implement existing knowledge to improve care – rather than to develop new knowledge – answer "no".*	☐ Yes ☐ No
3	Are researchers who have no ongoing commitment to improvement of the local care situation (and who may well have conflicts of interest with the patients involved) involved in key project roles? *Generally answer "yes" even if others on the team do have professional commitments. However, where the project leaders with no clinical commitment are unaffiliated with the project site, it may be that the project site is not engaged – and does not require IRB approval/oversight – even if the project leaders' roles do require IRB oversight at their institutions.*	☐ Yes ☐ No
4	Is the protocol fixed with a fixed goal, methodology, population, and time period? *If frequent adjustments are made in the intervention, the measurement, and even the goal over time as experience accumulates, the answer is more likely "no."*	☐ Yes ☐ No
5	Will there be delayed or ineffective feedback of data from monitoring the implementation of changes? *Answer "yes" especially if feedback is delayed or altered in order to avoid biasing the interpretation of data.*	☐ Yes ☐ No
6	Is the project funded by an outside organization with a commercial interest in the use of the results? Is the sponsor a manufacturer with an interest in the outcome of the project relevant to its products? Is it a non-profit foundation that typically funds research, or internal research accounts? *If the project is funded by third-party payors through clinical reimbursement incentives, or through internal clinical/operations funds vs. research funds, the answer to this question is more likely to be "no."*	☐ Yes ☐ No

Adapted from Hastings Center, "The Ethics of Using Quality Improvement Methods to Improve Health Care Quality and Safety" (June 2006)

If the weight of the answers tends toward "yes" overall, the project should be considered "research" and approved by an IRB prior to implementation. If the weight of the answers tends toward "no," the project is not "research" and is not subject to IRB oversight unless local institutional policies differ. Answering "yes" to sequence #1 or #2 – even if all other answers are "no" – typically will result in a finding that the project constitutes research. *It is important to consult with your local IRB if you are unsure how they would handle a particular case, as the analysis of the above issues cannot always be entirely objective and IRB policies and approaches vary significantly.*

Appendix B

Quality Improvement Project Ascertainment Checklist (QuIPAC©)

This checklist will help you determine whether a proposed project is in fact QI or potentially human subjects research.

Consideration	Question		
Purpose	Is the primary aim or motive of this activity either to: • Improve care *right now* for the next patient seen? **or** • Improve efficiency or operations?	☐ Yes	☐ No
Rationale	Is there sufficient evidence for, or acceptance of, this approach to support implementing this activity or to create practice change, based on: • Consensus among clinician or clinical team, • Consensus statements, or • Literature?	☐ Yes	☐ No
Methods	Are the proposed methods flexible and customizable, and do they incorporate rapid evaluation, feedback, and incremental change?	☐ Yes	☐ No
Risk	Is the risk related to the project minimal (see below) and no more than usual care and to privacy or confidentiality?	☐ Yes	☐ No
Benefits	Chiefly participants at local institution, not society.	☐ Yes	☐ No
Participants	Will the activity only involve participants (patients, parents, or institution faculty/staff) who are ordinarily seen, care for, or work in the setting where the activity will take place?	☐ Yes	☐ No
Results	Generalizability of results is possible, but not the main intent of the activity.	☐ Yes	☐ No
Funding	Is the project funded by any of the following? • A manufacturer with an interest in the outcome relevant to its products • A nonprofit foundation that typically funds research (see below) or by internal research accounts • An outside organization with an interest in the results	☐ Yes	☐ No
Dissemination	Are you planning to disseminate the **results**, not process, of the activity?	☐ Yes	☐ No

If all of the check marks are inside the shaded grey boxes, then the project is likely quality improvement and not human subjects research. Regardless or the categorization of the activity IRB approval should be sought. For applicable definitions, please see the following sections of §45 Part 46 of the Code of Federal Register (shorturl.at/gAIMP):

- §46.102(e) Human Subject
- §46.102(j) Minimal Risk
- §46.102(l) Research

Appendix C

Gilbert and Calhoun's Research Algorithm©

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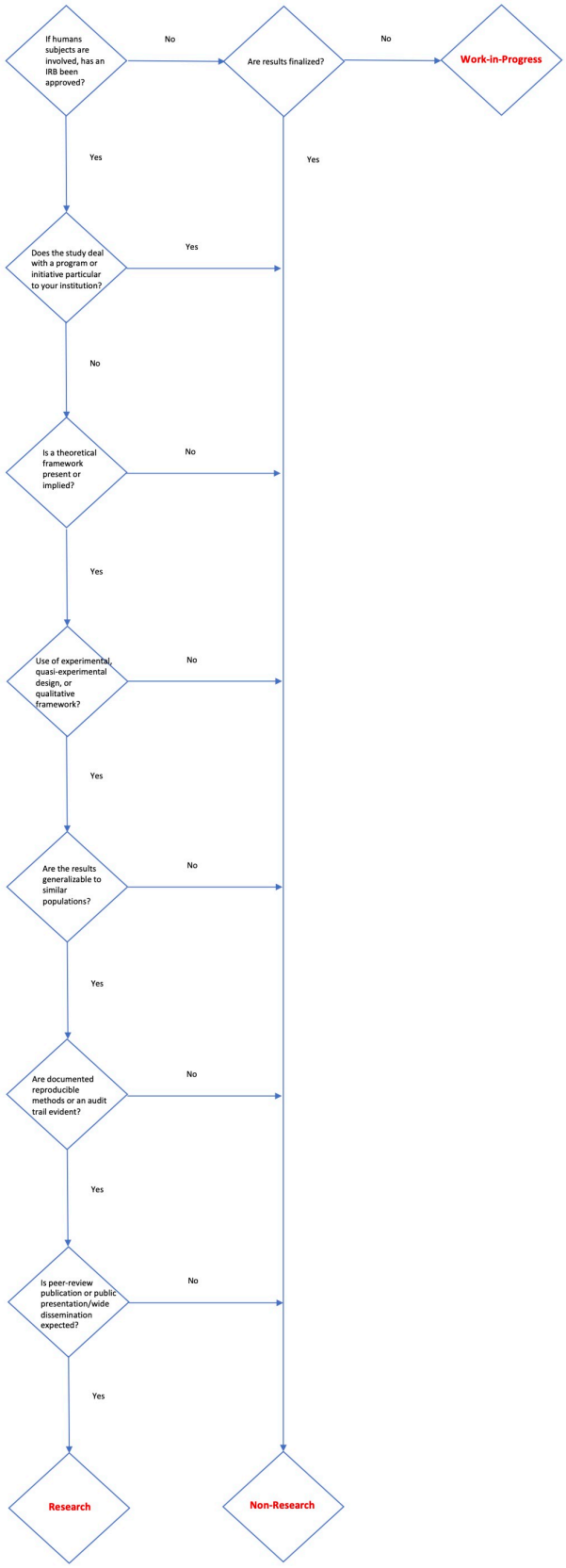

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