



The Slippery Slope

Differentiating Between Quality Improvement and Research

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As hospitals strive to create strong work environments for nurses, many use the core requirements for Magnet designation to enhance and build new programs in research and evidence-based practice into patient care and operational processes. The problem is the use of quality improvement projects in these efforts as evidence of a healthy “research” program. This confusion can lead to 3 major consequences: (1) poorly designed and interpreted studies; (2) lack of consideration of subject rights; and (3) Institutional Review Board or other regulatory sanctions for noncompliance with federal, state, and local law and institutional policies. The purpose of this article is to differentiate between research and quality improvement, explore the potential risks of confusing quality improvement with research, and suggest criteria by which to determine the difference.

As nursing science advances, organizations with rigorous nursing research programs lead the generation of new knowledge in our field. Magnet hospital recognition is one of many catalysts for increasing interest in conducting nursing research. Magnet hospitals are known for enhanced nurse

work environments, better nurse recruitment and retention, and improved patient outcomes.¹ One of the core requirements for Magnet designation is evidence of the incorporation of research and evidence-based practice into patient care and operational processes.¹ Hospitals that aspire to Magnet status actively develop or enhance their nursing research and evidence-based practice programs to comply with these core requirements. The challenge is in the use of quality improvement (QI) projects as evidence of a healthy “research” program and the potential consequences of not considering and understanding the differences between QI and human subject research. Any QI used as research evidence would require the approval of an Institutional Review Board (IRB).

As nurses become more sophisticated in their approach to QI efforts, they have become more rigorous in their approach, the analysis of results, and use of established measures as metrics. In addition, nurses have expanded the design of these projects from trend analysis to the use of comparison groups and evaluative designs. However, rigorous design and sample factors alone do not distinguish human subject research projects from QI.² As nursing science evolves, the line between QI and research is an important fundamental distinction that must be understood and respected.

At a recent national conference, 2 separate presenters advocated for use of QI data as evidence of nursing’s engagement in active research. Although this belief is widely held, it presents a *slippery slope* for nursing. This confusion can lead to 3 major consequences: (1) poorly designed and interpreted studies; (2) lack of consideration of

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subject rights; and (3) IRB or other regulatory sanctions for noncompliance with federal, state, and local law and institutional policies.

The danger of viewing QI as “research” has the potential to become an escalating issue as nurse executives strive to implement evidence-based practice and nursing research programs in their healthcare organizations. These executives face an uphill battle to change perceptions in their own healthcare communities. In general, nurses and administrators in hospitals perceive research to be at a low level of development,³ and nurses consider research competencies for managers to be of lower importance than clinical or managerial tasks.⁴ Building a research program in community hospitals requires a commitment by hospital leadership and a strategic plan to ensure that all components of necessary research infrastructure are in place.⁵ This infrastructure must be in place before research can proceed, and it includes the following (at a minimum): a plan for mentorship of staff, a process for oversight, a human research participant protection program (if none exists) and affiliation with an IRB, a nursing approval process, the availability of a statistical program to analyze the data or links with consultants with corresponding analytic competencies, a clinical space to store research data in a confidential site, and a commitment to give nurses time to conduct studies.⁵

Quality Improvement or Research?

Table 1 describes the basic definitions of research and QI. Research is defined by the Department of Health and Human Services as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”⁶[45 CFR 46.102(d)] Generally speaking, this definition includes any

project that has the purpose of learning something that may apply to populations or administrative units beyond the primary site or setting of the research. This objective is distinct from that of QI projects.

Quality improvement in healthcare is a process by which individuals work together to improve systems and processes with the intention to improve outcomes.⁷ It includes setting organizational priorities for problem-prone processes. For example, appropriate QI project objectives could include the following: improving compliance with preoperative screening requirements, enhancing delirium screening to better intervene to prevent or diminish the intensity of delirium, and implementing a chemotherapy checklist to reduce errors for the patients who receive chemotherapeutic agents in your hospital.

Quality improvement is not intended to generalize knowledge but to improve care for a specific population, usually in a limited application (eg, in a specific nursing unit or clinic). It is a process of self-monitoring and self-assessment. Results are applied in an effort to improve a process or practice. Trends are monitored with process improvement tools, such as run charts, and standardized reports.

The distinct and fundamental difference between QI and research is the purpose. Research is conducted to generate new knowledge that may be applied generally.⁶ Quality improvement is conducted to improve care for a specific healthcare facility population.⁷ When, at project inception, a team intends to publish an article related to the QI process or findings, the purpose becomes less clear. The elemental question then emerges: Is the publication intended to describe lessons learned (QI), or is it intended to demonstrate that a new strategy or intervention produces specific outcomes (research)? This question is fundamental because the intent and the responsibility for QI and research are distinctly different. Lack of definition of the team’s intent as to the project’s purpose at the beginning of the project creates potential vulnerability in a number of ways. Table 2 compares the use of a QI framework (Plan-Do-Study-Act) with a research approach to a clinical question.

The Risks of Confusing Quality Improvement and Research

There are a variety of issues associated with confusing QI and research. These include risk to the individual being studied (the subject, if research; the patient/family or staff, if QI), to the organization,

Table 1. Definition of Research and Quality Improvement

Term	Definition
Research	A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. ⁶
Quality improvement	A process by which individuals work together to improve systems and processes with the intention to improve outcomes. ⁷

Table 2. Comparison of Plan-Do-Study-Act Quality Improvement and Research Approaches to a Clinical Question

PDSA	Research
<p>Clinical Problem: Patient and family complaints related to restricted visitation policies have increased.</p>	<p>Conceptualization Research problem: There are variations in the implementation of the visitor policy across the hospital. It is unknown if these inconsistencies impact patient satisfaction or family anxiety. Hypothesis 1: Liberal visitation policies for adult patients decrease family anxiety. Hypothesis 2: Liberal visitation policies for adult patients increase patient satisfaction.</p>
<p>Plan</p> <ul style="list-style-type: none"> • Preliminary measure: documented patient satisfaction and visitor anxiety scores • Test of change: for 2 weeks, implement new visitation policy to encourage visitation on a surgical unit • Postmeasure: documented patient satisfaction and visitor anxiety scores 	<p>Design and Planning</p> <ul style="list-style-type: none"> • Conduct a quasi-experimental study of liberal versus restricted visitation policies • Experimental group: 50 subjects admitted a unit with liberal visitation; control group: 50 subjects admitted to a unit with restricted visitation
<p>Do</p> <ul style="list-style-type: none"> • During the pilot, incidental findings included that the effects of visitation on the continuity of nursing care needed to be considered and that nurses' attitudes regarding liberal visitation were not always positive. 	<p>Method/Analysis</p> <ul style="list-style-type: none"> • Coinvestigators will obtain informed consent from subjects. • Measures: family visitor subject scores on 0-10 numeric Anxiety Scale and patient satisfaction scores to be obtained on subject discharge on validated Visitor Satisfaction survey instrument • Analysis: <i>t</i> tests for significant differences in mean scores
<p>Study</p> <ul style="list-style-type: none"> • Found 7 fewer episodes of documented anxiety in waiting family members after implementation of liberal visitation policy • 94% of patients were either satisfied or highly satisfied with the overall PACU experience. 	<p>Results</p> <ul style="list-style-type: none"> • Family subjects in the liberal visitation group had significantly less anxiety ($P < .05$) than subjects on the restricted visitation PACU. • Patients in the liberal visitation PACU were significantly more satisfied than those on the restricted visitation unit ($P < .01$).
<p>Act</p> <ul style="list-style-type: none"> • Communicate results of this PDSA cycle. • Spread successful change to other units. 	<p>Conclusions</p> <ul style="list-style-type: none"> • Liberal visitation policies decrease family anxiety and increase satisfaction in adult patients.

PACU indicates American Society of PeriAnesthesia Nurses.

to the nursing investigator, and to nursing as an enterprise. First and of great importance is the risk to the subject or patient.

Risk to Subjects (Patient/Family)

Engagement in QI requires the design of a measurement plan that is reasonably collected while protecting the confidentiality of patient data. Staff in healthcare organizations complete training required by the Health Insurance Portability and Accountability Act regulations to understand their responsibility in the protection of patients' health information during the care process. Responsibilities for handling patient information also apply to the QI process as part of these processes of care. After QI data are collected on the topic of interest, results are aggregated and trends are observed over time. The patient or patient population is expected to benefit directly from these observations, as the goal is to improve healthcare delivery.⁸

Although research generates knowledge to improve outcomes for populations, the subject in a research study may or may not benefit from participation. The study goal is the production of new knowledge systematically. The knowledge is the primary goal, not the care of the individual subject. Because the participant's individual benefit is NOT the primary objective, the investigator's responsibility extends beyond issues of confidentiality.

These responsibilities include assuring that the research design is scientifically sound and does not unnecessarily expose participants to risk, that the risks to subjects are reasonable in relation to anticipated benefits and the importance of the knowledge expected to result, that the selection of participants is fair, that informed consent is sought from each prospective participant, that the participant's privacy and other rights are protected, and that vulnerable populations are protected against coercion or undue influence. These basic rights are

outlined in the Belmont Report produced by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and are codified in federal regulations.⁹

The basic rights of all subjects outlined in the Belmont Report include the following: *respect for persons* (voluntary subject participation and protection of vulnerable people), *beneficence* (decisions are respected and participants are protected from harm), and *justice* (benefits and burdens of research are distributed fairly).⁹ These basic rights are embraced by nursing and supported in the American Nurses Association Scope and Standards of Practice,¹⁰ which outlines the registered nurses' active participation in research activities appropriate for the nurse's position and education.¹¹

When participating in research at the basic level, activities may include identifying clinical problems, collecting data, analyzing findings, and incorporating findings.¹¹ Nurses with a degree at the master's level are prepared to participate as a research team member.¹¹ Doctoral study prepares nurses to conduct research. Beyond research methods, design and theory, and advanced analysis, nurses (and anyone else) who wish to conduct human subject research need to have specific training to understand the responsibilities that a principal investigator (PI) of a human subject research study assumes. The PI must conduct the study in accordance with the policies of the PI's institution and be compliant with the requirements of the Office of Human Research Protection (OHRP) and the Food and Drug Administration (if applicable). The OHRP and Food and Drug Administration have the authority to audit any study or institution to ascertain whether a PI is meeting those responsibilities (see <http://www.hhs.gov/ohrp/compliance/ohrpcomp.pdf>) and to impose sanctions for failure to comply. Thus, each investigator must be trained to meet these standards. This requires basic education in the protection of human participants enhanced through mentorship by an experienced investigator. In 2000, the National Institutes of Health began requiring investigators and other key research personnel to complete formal training and education in human subjects protection (<http://www.nih.gov/sigs/bioethics>). Without this guidance, there is an unintended potential for human subject research violations and resulting noncompliance sanctions.

The PI of a study is responsible for complying with institutional, regulatory, and legal requirements in the conduct of that study. The IRB review complements the PI in that compliance effort. "When conducting human research funded by the Department of Health and Human Services (DHHS)

or any one of the federal agencies, which has adopted the Common Rule, review and approval by an IRB, is required before the research may begin."⁶[45 CFR 46.103(f)] "The IRB is an independent committee with members that may include non-scientists and ethicists, in addition to physicians and nurses with special expertise, and at least one member who is not otherwise affiliated with the institution."⁴[45 CFR 46.107(d)] The IRB is responsible for safeguarding the rights and welfare of human subjects by "ascertaining the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice."⁴[45 CFR 46.107(a)] Robert Levine, in his book *Ethics and Regulation of Clinical Research*,¹²(p.325) citing the Commission Report on IRBs at page 527, describes the role of IRBs as conceived by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the author of the Belmont Report:

The ethical conduct of research involving human subjects requires a balancing of society's interests in protecting the rights of subjects and of developing knowledge that can benefit the subjects or society as a whole...Investigators should not have the sole responsibility for determining whether research involving human subjects fulfills ethical standards. Others who are independent of research must share this responsibility, because investigators are always in positions of potential conflict by virtue of their concern with the pursuit of knowledge as well as the welfare of the human subjects of their research.

Review and approval by an Institutional Review Board are dependent on a variety of factors that include the following: the clearly stated research purpose and design, weighing the risk to subjects against potential benefits, the importance of the knowledge to be learned, consideration of the recruiting and consent processes, and evaluation of provisions for additional protections for vulnerable populations. A research project protocol that does not address these factors will not be approved by the IRB. Hence, investigators cannot begin to implement the protocol until all questions are addressed and IRB approval is obtained. Therefore, when contemplating human subject research, investigators must consider all these issues that QI project teams may not. The PI must have training and competency in conducting human subject research and must assure the IRB that the research team has also received training, is knowledgeable about the protocol, and is competent to undertake these responsibilities.

Risk to Organizations

Human research may be conducted in a variety of organizations, both public and private. "In medical centers that receive federal funding for research, human subject research is conducted under a Federal Wide Assurance that guarantees that the organization complies with specific responsibilities."^[45 CFR 46.103(a)] This assurance is similar to a contract between the medical institution and the government, binding all its departments and employees who conduct research to the principles of the Belmont Report and the human subject research regulations. Failure to comply with these standards may bring federal sanctions to the individual researcher and to the institution itself. In addition to the federally imposed responsibilities, each state has its own laws and regulations on the conduct of research that must be understood and respected. Legal consequence for failure to adhere to state and local laws may also introduce risk to the organization.

Investigations by the OHRP often result in institutional review of research practices, and one such review was spawned by a case that involved the boundary between "quality improvement" and "research." In this example, a QI study was conducted in which current patients were treated differently than they otherwise would have been in order to collect information that the investigators intended to use to consider modification of the treatment of future patients.¹³ Presentation of their data at a national meeting prompted an OHRP review that determined that this project did constitute research that was more than negligible risk. IRB review and informed consent from the subjects were required.

Risk to Nursing

For nurses, there is a professional and personal risk. Professionally, conducting research under the umbrella of QI will diminish the ability to interpret, generalize, or publish findings. Poorly designed small studies that have not received rigorous scientific review will not provide useful knowledge that can be generalized to other settings. Although a number of poster and oral presentations address QI projects, the evidence presented is considered to be "practical lessons learned" and to be a low level of translatable evidence.

Nursing science advances through the conduct of research. Small studies with uninterpretable results will not provide the knowledge required to determine the relationship between interventions and outcomes. Such studies not only diminish the

credibility of nursing research but also use nursing resources (time and money) that do not result in a productive outcome.

The second issue for nursing is the impact on the individual. If a nurse would like to develop expertise and begin to publish, using QI contributes a lower level of evidence to the field as previously discussed. When QI processes or results are published, they must be represented as QI, not as research. Peer-reviewed journals want evidence of an acceptable ethical standard and will ask potential authors if they obtained the IRB approval of their projects before considering articles for publication. Nurses who have pursued research projects without the IRB approval have not only violated the ethical standard but also seriously compromised their ability to publish the results.

If a nurse is uncertain whether a project is QI or human research, the wisest course is to obtain guidance from the IRB. A letter from an IRB chair to state that the project is QI and is not considered human subject research will be sufficient to indicate that IRB review is not required.

Criteria for Determining Quality Improvement or Research

There are 3 factors that help distinguish QI and research. The first factor is the intent of the investigator as defined by the expressed purpose of the proposed project, specifying who may benefit from the project.⁸ On the one hand, the purpose of research is to generate knowledge that may have broad application. In contrast, the purpose of QI is to improve care processes within a specific unit or organization. Quality improvement is a management tool. If the intent of the investigator is to design a project to benefit individual patients served by a specific unit or organization, that project is most likely QI. If the intent of the investigator is to assess outcomes of a controlled study in order to produce generalized knowledge and subjects involved may or may not benefit directly from the knowledge gained, then the project is research.⁸ Sometimes determining the intent is difficult, but the study objective should provide insight. If the project seeks to test an existing process, it is most likely QI. If, however, the aim is to evaluate an innovation to an existing process, to study something completely new, or to analyze a process that has not yet been subjected to rigorous scientific analysis, then the project is research, not QI.

The second major factor distinguishing QI from human subject research concerns the risks and burdens imposed on the individual participating in the project.⁸ In QI, the objective is to benefit those patients who are served by the clinical subdivision; thus, the risk of “participation” is the same as the risk of receiving clinical care. In research, the subjects put themselves at risk of harm knowing in advance that personal benefit may not result. Thus, the informed consent process is critical to the research enterprise. Additional risks or burdens may be incurred by each individual subject to produce research results that may be generalizable across a broader population.⁸

The third factor that determines the categorization of the project as research or QI relates to the responsibility for oversight. A decision grid adapted from Solberg et al¹⁴ with 2 major criteria added from Casarett et al⁸ will frame the subsequent discussion (Table 3).

Intent—Who Benefits?

Consider first the investigator’s intent. Quality improvement may benefit patients, staff, or providers. The purpose is to understand and improve a

process or experience or evaluate changes within a specific unit or organizational population as a management tool. Research is intended to provide knowledge that is generalizable to populations for use by clinicians or the broader scientific community, not to assess the success of an existing process for purposes of system improvement.

Some argue that this distinction can be quite arbitrary and that there is no meaningful difference between the collection of data that have local implications and data that have national implications.¹³ At the time of a QI project’s inception, investigators often do not know whether results of the project will be publishable or generalizable outside their institution. Teams should err on the side of caution and classify more QI activities as research.

Modern QI collaboratives use new knowledge and innovation obtained through research to plan and test local changes in healthcare.¹⁵ The resulting knowledge gained through the tests of change in local areas is then spread both within and outside the organization. The expectation exists that successful QI stories are shared; hence, a conflict of interest may occur when the intent is, indeed, to generalize results, regardless of how widely they will be disseminated.

Table 3. Comparison of Research and Quality Improvement*

Defining Questions	Quality Improvement	Research
Intent		
Who will this research benefit?†	Patients Staff Providers	Clinicians Scientific community Subjects (on occasion)
What is the purpose?	Understand and improve a process or patient experience Evaluate changes	Generate knowledge Generalize knowledge
How large is the scope of interest?	Specific unit, or patient population within an organization	General population
Additional burden or risks†		
How are the processes or outcomes measured?	Measures are limited, simple, and easy to use and administer	Measures are complex Increased time is required to fill out the measure Measures require a detailed administration plan Estimates of reliability, validity, specificity, and/ or sensitivity are required
What is the study timing?	Rapid cycle	Planned and longer
How are extraneous variables handled?	Acknowledged but not measured	Controlled and/or measured
How large is the sample?	Small but large enough to observe changes	Tight protocol control Size is based on estimates of adequate power (or saturation)
How are data collected?	Minimal time, resources, and cost	Complex, tightly controlled, plan for resources are constructed
Regulated by	Organization	Organization, OHRP, FDA, state, and local laws

OHRP indicates Office for Human Research Protections; FDA, Food and Drug Administration.

*Adapted with permission from the ©Joint Commission Resources. The three faces of performance measurement; Improvement, accountability, and research. *Journal on Quality Improvement*. 1997;23(3):135-147.

†Criteria from Casarett et al⁸ included.

Burdens and Risks to the Patient or Subject

The second issue is the level of burden and risks imposed on the patient or subject.⁸ Quality improvement usually employs limited measures that do not take a long time to complete or are not difficult to administer.¹⁴ A signed informed consent, typical in research, is not required for QI. Improvement is expected in brief time intervals that are measured and reported back to the clinical area through a rapid cycle intervention. Beyond data collection, the responsibilities of the investigator to the patient are that of standards of usual clinical care.

In contrast, the research study subjects must understand that they are volunteers in the project, that their direct personal benefit is not the primary concern, and that they may withdraw from a study at any time. Informed consent is an essential protection and generally is required for all research studies. The burdens of research to the participant may be time commitment and inconvenience, as well as risk (eg, physical, psychological, legal, financial), often with no or little prospect of direct benefit. "The researcher has a responsibility to protect these subjects, and to comply with institutional, regulatory, and legal requirements."^[45 CFR 46.103(b)(1); 45 CFR 46.107(a)]

The specific topic of the research should also be considered.¹⁴ Quality improvement generally addresses current practices to determine their effectiveness in a clinical setting. There is usually no attempt to control all variables that may affect the outcome, and the sample is not intended to be large enough to determine a statistically significant difference. Quality improvement is a component of organizational responsibility. Leaders are charged with setting priorities for QI and ensuring that the multiple hospital providers of care, treatment, and services collaborate to plan and implement improvement activities.¹⁶ Healthcare organizations have the responsibility to measure and improve practice. This activity can be planned at specific levels of the organization, such as nursing units or departments, or organization-wide. Quality improvement reporting is an internal process.

Research attempts to test existing practices in new ways, compare standard and nonstandard approaches to care, evaluate new or modified healthcare strategies or therapies, or pursue innovative theories in an effort to extend current knowledge.¹⁷ Research uses measures that have established reliability and validity or develops new tools, and protocols provide detailed instructions to ensure a high level of standardization. Multiple

measures may be used which require longer periods to complete. The sample is estimated at a level required to find statistical significance if a difference exists. There is an attempt to implement a design that controls for as many variables that may affect the outcome as possible. This may require randomization to different groups and include a control or no intervention group.

Oversight of Quality Improvement and Research

The third factor is dependent on the categorization of the project as research or QI and relates to the responsibility for oversight. The organization sponsoring the interaction or intervention with the patient or subject and the individual researcher is responsible for safety oversight of both the QI and research process. Researchers, however, must also comply with state and federal laws and regulations related to the conduct of human subject research. The distinguishing factor as described in the prior section on risk to the organization is that human subject research is conducted under Federal Wide Assurance between the Department of Health and Human Services, through OHRP, and the research institution. The Federal Wide Assurance certifies that the institution will conduct research in accordance with federal laws and regulations. "Failure to comply with these requirements puts the institution at risk of government sanction—including the possibility of shutting down all research."^[45 CFR 46.103(a)] These federal requirements are in addition to state and local laws and regulations.

The intent of the investigator and subsequent benefits to the patient or subject, risk and burden imposed on the patient or subject because of the intent of the project, and the subsequent responsibility for oversight are 3 important factors that distinguish QI and research. Next, we will describe 2 exemplars to differentiate research and QI.

Exemplars

Quality Improvement

The QI committee has reviewed the incidence of pressure ulcers by unit for its hospital. Data had been collected during a period of 24 hours by nurses on each unit by assessing the skin of each patient on the designated day. One unit has a high incidence of what is thought to be hospital-incurred pressure ulcers. The committee requests that the charts for patients identified in the review be examined to determine whether these pressure ulcers were hospital acquired and to identify their location and the factors that are related to pressure ulcer development

so that a plan can be devised to reduce the incidence of nosocomial pressure ulcers.

This is an example of a QI project. The organization has a quality focus on decreasing the incidence of pressure ulcers. The observation was conducted as part of standard organizational business for the purpose of improving care in an area identified as a problem. No risk is imposed on the patients because information was collected and aggregated in a de-identified way. The patients in the hospital at risk will benefit by improved processes because of this review.

Research

Staff members from surgery have studied factors related to pressure ulcers. Through a literature review, they discover that there is no assessment tool for preoperative patients that include all of the factors appropriate for the perioperative area. They calculate the number of patients needed to complete an analysis to determine the significant predictive factors for pressure ulcers so that they can pull medical records for review, complete the analysis, and construct an instrument to screen preoperative patients that could be used in various settings.

This is an example of research. The intent of the investigators is to create a screening tool for perioperative patients to identify predictive factors that lead to pressure ulcers. It would require a large number of chart reviews, and although patients at this facility may benefit, the purpose is to generalize the results to other perioperative areas. The sample would include those patients that acquired a pressure ulcer and those that did not, so that the likelihood of developing a pressure ulcer can be

calculated. Additional risks to subjects include confidentiality. In addition, more subjects are required for the sample that includes controls or comparisons that would have not been included in the data for a QI study.

Conclusion

The difference between QI and research is not always clear. The consequences of misrepresenting QI as nursing research result in poorly designed and interpreted studies, potential for lack of consideration of subject rights and IRB or other regulatory sanctions for noncompliance with federal, state, and local law and institutional policies. The differences between QI and research are framed by criteria, which include identifying the intent and who benefits by the knowledge to be gained from the project and assessing whether additional risks or burdens are assumed by the human subject to gain that knowledge.⁸ Finally, the third factor relates to the investigator's responsibility for oversight and required compliance of research with organizational policies and local, state, and federal regulations.

Nurses should consider these criteria carefully before proceeding with any project and should seek the advice of their IRB if there are questions. The consequence for failing to recognize the distinction between QI and human subject research is considerable for nurses personally and professionally. A clear understanding of the differentiation between QI and research will enhance evidence-based practice efforts that focus on improvement and strengthen studies intended to generate knowledge through research.

References

1. American Nurses Credentialing Center. *Magnet Recognition Program*. Silver Spring, Md: American Nurses Credentialing Center; 2005.
2. Reinhardt AC, Ray LN. Differentiating quality improvement from research. *Appl Nurs Res*. 2003;16(1):2-8.
3. Newhouse RP, Mills ME. Enhancing a professional environment in the Organized Delivery System: lessons in building trust for the nurse administrator. *Nurs Admin Q*. 2002;26(3):67-75.
4. Kondrat BK. Operating room nurse managers—competence and beyond. *AORN J*. 2001;73(6):1116-1130.
5. Newhouse RP, Mills ME. Research in the community hospital. *J Nurs Admin*. 2001;31(12):583-587.
6. Department of Health and Human Services. Code of Federal Regulations Title 45 Public Welfare Part 46: Protection of Human Subjects, current through April, 2005. Department of Health and Human Services.
7. Committee on Assessing the System for Protecting Human Research Participants. *Responsible Research: A Systems Approach to Protecting Research Participants*. Washington, DC: The National Academies Press; 2002.
8. Casarett D, Karlawish JH, Sugarman J. Determining when quality improvement initiatives should be considered research: proposed criteria and potential implications. *JAMA*. 2000;283(17):2275-2280.
9. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report*. DHEW Publication No. (OS) 78-0013 and No. (OS) 78-0014. Washington, DC: Department of Health, Education, and Welfare; 1979.
10. American Nurses Association. *Nursing: Scope and Standards of Practice*. Washington, DC: American Nurses Association; 2004.
11. Council of Nurse Researchers, Council of Nursing Practice. Education for participation in nursing research. American Nurses Association. 1994. Available at: <http://www.>

- nursingworld.org/readroom/position/research/rseducat.htm. Accessed September 27, 2005.
12. Levine R. *Ethics and Regulation of Clinical Research*. 2nd ed. New Haven: Yale University Press; 1988.
 13. Doezema D, Hauswald M. Quality improvement or research: a distinction without a difference? *IRB Ethics Hum Res*. 2002;24(4):9-12.
 14. Solberg LI, Mosser G, McDonald S. The three faces of performance measurement; improvement, accountability, and research. *J Qual Improv*. 1997;23(3):135-147.
 15. Ovretveit J, Bate P, Cleary P, et al. Quality collaboratives: lessons from research. *Qual Saf Health Care*. 2002;11(4): 345-351.
 16. Joint Commission for Healthcare Organizations. *Comprehensive Accreditation Manual for Hospitals: The Official Handbook*. Oakbrook Terrace, Ill: Joint Commission for Healthcare Organizations; 2004.
 17. National Bioethics Commission. *Ethical and Policy Issues in Research Involving Human Participants*. Bethesda, Md: National Bioethics Advisory Commission; 2001.