Development of an Institutional Review Board Preapproval Process for DNP Students: Process and Outcome

Sarah L. Szanton, PhD; Holly A. Taylor, PhD; and Mary Terhaar, DNSc

ABSTRACT

As Doctor of Nursing Practice (DNP) programs proliferate, effective collaboration with institutional review boards (IRBs) is important to protecting human subjects. It is particularly important that faculty and students recognize which DNP students' projects should be considered as "human subjects research" or "quality improvement." The former require IRB review, whereas the latter may be eligible for expedited review or may be considered exempt. We report outcomes following implementation of a combination of didactic training, one-to-one consultation, and a decision support protocol to improve preparation for and collaboration with the IRB at a large university. In the first year of using this protocol, 53% of projects were deemed human subjects research and received IRB review. The other 47% were deemed quality improvement projects and did not require IRB review. We offer our experience as an approach for teaching students how to protect the subjects included in their quality improvement activities.

Currently, Doctor of Nursing Practice (DNP) programs are flourishing, and 153 programs across the United States report a total enrollment of 7,034 students (Raines, 2010). This number is expected to increase significantly, as the American Association of Colleges of Nursing (Raines, 2010) indicated that all entering nurse practitioners should have a practice doctorate as of 2015. The DNP degree at Johns Hopkins University School of Nursing emphasizes the translation of evidence generated through research as a means of achieving practice improvement. The scholarly works produced by our DNP students vary and are referred to by a variety of terms, including *practice-based research*, *translation research*, and *quality improvement* (QI). We use the term QI to describe the work reported in this article.

In other DNP programs, the students' capstone projects range from writing case studies that link evidence to direct patient care to performing secondary analysis of extant data sets, assisting in conduct of research, and writing state-of-the-science papers, among other options. This article focuses on capstone projects that translate evidence into practice, as this is the focus of the Johns Hopkins University School of Nursing's DNP program and also because these projects have particularly complex review needs with regard to ensuring the responsible protection of human subjects.

Although there is an ongoing debate regarding whether QI activities should be considered human subjects research for the purposes of regulatory review and oversight, we believe the ethical principles of respect for persons, beneficence, and justice should guide the conduct of QI (The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). The process of translating evidence into practice requires care to avoid risk to patients, providers, and institutions when any or all of such are the subject of QI. Although the local institutional review board (IRB) is responsible for the review and oversight of human subjects research (HSR), there is no equivalent entity tasked with the review of QI. This situation can lead to referral to the IRB of QI activities that are technically not human subjects research, thus placing unnecessary demands on the limited resources available to IRBs. The distinction between QI and HSR may vary from institution to institution.

The purpose of this article is to report an innovative process designed to (a) protect participants in DNP scholarship-related activities, (b) distinguish QI from HSR, (c) ensure the readiness of project proposals for consideration by the IRB, and

(d) appropriately refer projects to the IRB. We provide data concerning the adoption, refinement, and implementation of the review process that was applied to DNP projects between 2008 and 2011 at Johns Hopkins University School of Nursing, introducing decision principles and practical resources to aid in decision making. The goal of this work was to systematize and streamline the decision process, teach DNP students about the critical role of ethical review and oversight, guide students in preparing appropriate documents, and offer support throughout the process. The innovation described in this article is the adaptation of a decision support tool for use by students and faculty. This tool can help individuals reliably and consistently discriminate between projects that require review by the IRB and those that would be considered QI activities. In both cases, the subjects' rights are protected. The innovations associated with the teaching of the IRB-related processes are: (a) all students are instructed in how to think about translation activities in the context of the rights of those involved, and (b) all students are taught how to apply this thinking to future decisions through the guidance of faculty who are on the IRB.

DNP Program

One of the primary objectives of the DNP degree is to produce practice scholars with the skills to evaluate and translate evidence to improve the health care delivered by individual providers and health systems. The Johns Hopkins University School of Nursing's DNP program is composed of 38 credits and can be completed in 2 to 3 years. A series of four capstone courses guides students through the application of core content to the completion of a significant, original, rigorous project in which they translate evidence into practice. Under the direction of a faculty advisor and clinical mentor, the students identify a significant practice problem, evaluate the evidence that addresses the problem, plan an evidence-based intervention, execute the intervention, conduct a rigorous evaluation, and disseminate the findings. The project, referred to as the Capstone Project, is the vehicle through which DNP students apply the content of the curriculum to advanced practice in nursing. During the second capstone course, students are introduced to HSR. The DNP program curriculum includes instruction by a Johns Hopkins University School of Nursing's faculty member (S.L.S.) who serves on the IRB. This faculty member covers the history of research ethics; the ethical principles that guide the conduct, review, and oversight of HSR (beneficence, autonomy, and justice); the federal regulations based on these principles; and the roles and responsibilities of the IRB (The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979).

Ethical Oversight of Quality Improvement

Current regulations that guide the conduct of HSR do not specify how investigators and IRBs ought to distinguish between HSR and QI. The IRB guidebook produced by the National Institutes of Health, Office for Protection From Research Risks (1993), which assists IRBs in the implementation of the regulations, makes no mention of the conduct of QI. In light of recent high-profile cases (Kaas et al., 2008; Miller & Emanuel, 2008; Pronovost et al., 2006) that hinged on the differences be-

tween QI and HSR, the U.S. Department of Health & Human Services, Office for Protection from Research Risks (n.d.) has created a frequently asked questions document to assist investigators and IRBs to determine whether a project is QI or HSR. Although the frequently asked questions document clarifies whether particular activities ought to be considered QI or HSR, it fails to provide the criteria for investigators and IRBs to apply to those activities that are not specified (National Institutes of Health, 1993). This lack of information has resulted in a need for innovations in teaching capstone students that can address the gap in such regulations.

As reviewed by Taylor, Pronovost, Faden, Kass, and Sugarman (2010), numerous commentators have suggested attributes to distinguish QI initiatives from HSR, as well as criteria to indicate when QI initiatives should be reviewed as if they were research. Some commentators suggested that risk (Grady 2007; Lynn 2004), or ways in which the activities are conducted, is unrelated to the interests of individual patients (Goldman et al., 2010; Lo & Groman, 2003; Lynn, 2004). Others suggested criteria for decisions used to indicate when particular initiatives should be reviewed as if they were research (Baily, Bottrell, Lynn, Jennings, & Hastings Center, 2006; Brett & Grodin, 1991; Lynn, 2004; Lynn et al., 2007). Although there is no consensus regarding the correct approach, there is an obvious need for oversight of at least some QI initiatives. In addition, many proposals rest on the current system of oversight of research, although others suggest the possibility of developing and using other approaches (Taylor et al., 2010). Because there is no consensus regarding the correct approach for distinguishing QI from HSR, our experience in mentoring students pursuing QI as a key component of their doctoral training has led us to adapt a set of internal guidance criteria developed by the Johns Hopkins University Medical Institutions Office of Human Subjects to help our students do so consistently (**Figure**).

History of IRB Review of DNP Proposals in Our Institution

During the first 2 years of the Johns Hopkins University School of Nursing's DNP program, 28 students completed the degree. All capstone projects were categorized as QI by DNP faculty and therefore were not submitted to the IRB for review. Many products of these early capstone projects were educational materials based on findings from evidence reviews. For example, one student prepared patient educational materials on urinary incontinence (Spencer, 2009). Several students conducted cohort studies to evaluate the adoption of new evidence-based clinical practice guidelines. For example, one student evaluated the implementation of a multidisciplinary approach to a medical service to reduce heart failure readmission rates (Ioannou & Dennison, 2010). In all, 28 students completed the program of study following this approach.

During the DNP program's third year, the program director decided that all DNP project proposals would be submitted to the IRB for review ($n = 30$). This decision was made because, as mentioned above, there is no complete consensus on how to treat QI activities, and the DNP director wanted to err on the side of protection for the patients and the systems in which they are served. Reviewing these proposals introduced the IRB to the
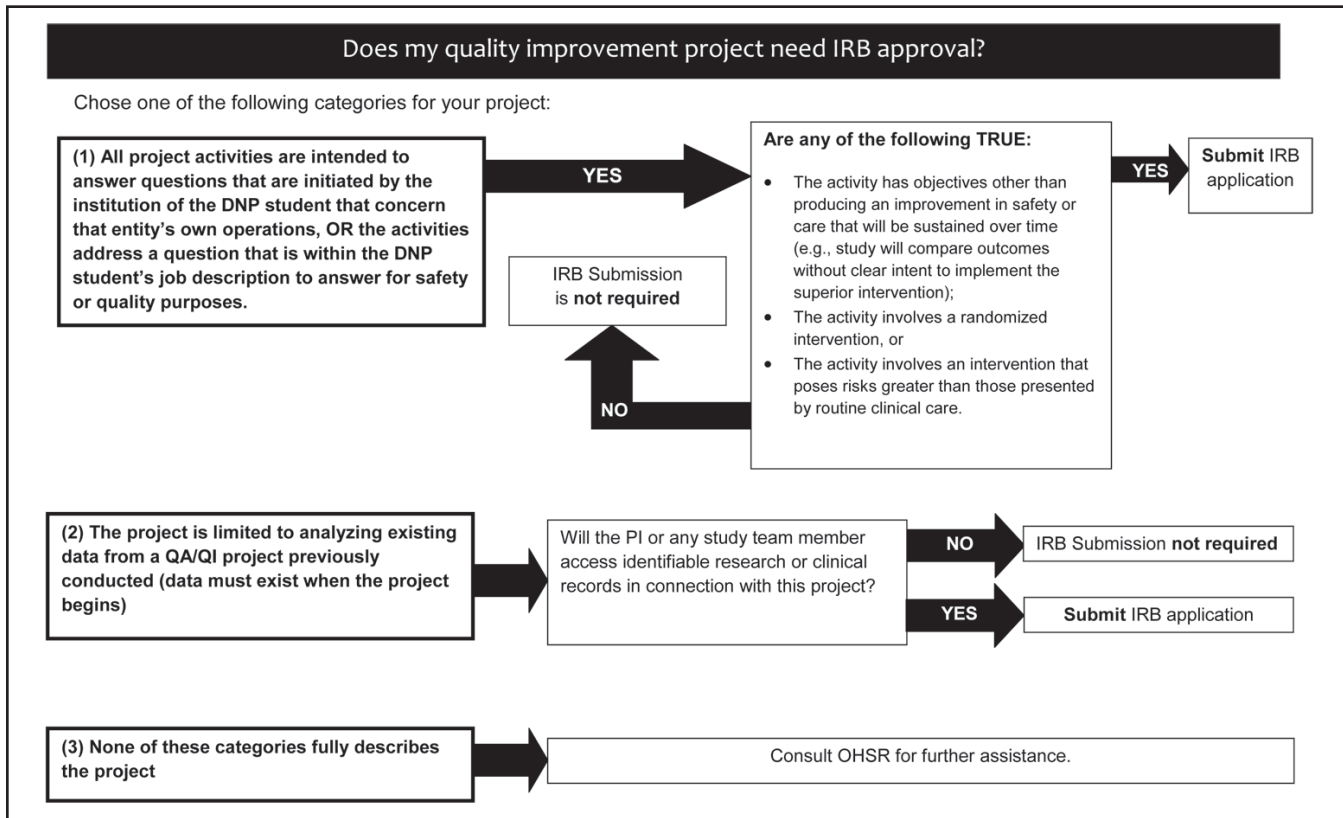
Figure. Decision report tool, which is applied to institutional review board (IRB) applications to ensure consistent review of proposals. Note. DNP = doctor of nursing practice; QA/QI = quality assurance/quality improvement; PI = principal investigator; OHSR = Office of Human Subjects Research.

nature of the capstone projects. As a result of this experience, during the fourth year of the DNP program (2010-2011), the school of nursing's faculty, in collaboration with IRB members, adopted a strategy to determine which capstone projects should be forwarded to the IRB for review. The strategy has five components and can serve as an innovative model for other DNP programs: (a) a school of nursing faculty member who serves on the IRB acts as liaison for the DNP program; (b) the faculty liaison provides instruction to the DNP students about the history, procedures, and responsibilities of the IRB; (c) the faculty liaison applies a decision guide to the proposals to support preview and appropriate referral with each student; (d) the faculty liaison provides consultation to students and advisors working to prepare capstone project proposals; and (e) the faculty liaison maintains a database of the status of all capstone projects and whether each was submitted to the IRB for review, and he or she reports to the DNP program director, curriculum committee, and IRB annually on the work of DNPs and the status of all capstone projects. Each component of the strategy is reported in more detail below.

School of Nursing's Faculty IRB Liaison

The IRB liaison (S.L.S.) is an active member of the IRB who regularly reviews proposals from the school of medicine and the school of nursing faculty that are expedited or of minimal risk. The role of liaison for the DNP program is a separate aspect of the workload carried as an active member of the IRB.

Instruction for DNP Students

Instruction is presented in a blended (in-person and online) format during the second capstone course led by the Johns Hopkins University School of Nursing's faculty liaison. Prior to receiving classroom instruction, students review materials on the history of HSR, the formation and responsibilities of the IRB, and the characteristics of QI and HSR. Students then engage in face-to-face discussion of the readings, with emphasis placed on comparing and contrasting QI and HSR. The students are guided through the use of online and print resources as they develop their capstone projects. As an in-class exercise, students apply the decision support tool to one student's project and determine whether it is QI or HSR. The tool leads the students through considerations of risk level, data confidentiality, subject vulnerability, and other IRB concerns. They also have in-class access to Web pages, such the U.S. Department of Health & Human Services, Office of Human Research Protection (http://www.hhs.gov/ohrp/), and the National Institutes of Health bioethics resources (http://bioethics.od.nih.gov/). The faculty member then circulates among groupings of four to five students to discuss the ethical aspects of each student's proposed capstone project. The focus is on understanding the responsibility of every nurse as a patient advocate, researcher, scholar,

and caregiver and how those responsibilities are related to the ethical conduct of capstone projects.

By the end of the first year, students have evaluated the evidence for the particular practice problem they choose to address, developed a plan to translate strategies supported by strong evidence into practice change, and crafted a detailed evaluation plan. Each student's capstone proposal is reviewed by the relevant faculty advisor and the IRB liaison to ensure its quality, completeness, and readiness for IRB review.

Decision Support

All students learn to prepare their projects for IRB consideration, including the preparation of a full IRB application. The faculty liaison applies the decision support tool to each application to ensure consistent review of proposals (**Figure**). On the basis of preview, students receive one of the following decisions:

- The project is QI (not HSR), introduces no risk, and does not require IRB review. Such projects are commonly within a DNP student's job description and concern the student's institutional operations. An example of this type of decision situation would be universally implementing an evidence-based pain assessment with each patient on the DNP student's inpatient unit. No randomization of pain assessments would occur, and the measurement would be a premeasurement–postmeasurement of an outcome such as satisfaction with care.

- The project is QI, but it involves some risk and should be submitted to the IRB for review. This type includes QI projects with the nursing staff who evaluate the performance of improvements. Because, as employees, the staff nurses are considered "vulnerable" (i.e., the staff nurses are employed at the place of the study and could risk losing their job or risk a breach of confidentiality), the IRB would want to be sure that the employer is adequately protecting the staff and thus would want to evaluate the protocol, even if it is QI.

- The project is HSR and should be submitted to the IRB. Such projects involve randomization of the intervention or patients to a particular intervention, involve risks beyond those of clinical care, or involve a comparison of the outcomes of two interventions without clear intent to universally implement the superior intervention.

Advisor and Student Consultation

The liaison is available for consultation in person and by e-mail while DNP students are preparing their projects. The liaison provides written and verbal feedback to the students, and he or she also tracks the progress of the workflow and IRB approvals for the DNP director and curriculum committee.

Database and Reporting

The liaison maintains a database of DNP students' capstone submissions and whether they are deemed HSR or QI, and this information is reported annually to the DNP director and curriculum committee. The liaison also works with the IRB staff to receive feedback about the process.

Outcome

Students, faculty, and IRB members have favorably reviewed this approach. Prior to the implementation of this process, the IRB submission and application revisions had been perceived as one of the most onerous parts of the DNP experience for both the students and the advisors. The new approach has lessened the amount of time each faculty advisor spends revising the IRB applications with their advisees. In the past year, 53% (9 of 17) of the students' projects met the criteria for submission to the IRB for review, and eight submissions were considered QI projects. Three students did not submit applications, or the applications were deemed not ready to submit.

Conclusion

Because the DNP is a new degree and there are many young programs, it is vital that faculty develop operations and processes to assure the quality of scholarship, rigor of work, and protection of human subjects. Structures and processes developed to protect human subjects participating in research must extend to protect patients participating in evidence-translation projects, when appropriate. Faculty members and students must reliably identify projects needing review by the full IRB without creating an unnecessary IRB burden by indiscriminately requesting review of large numbers of projects. As DNP programs become more plentiful, IRBs will become more accustomed to translation projects and will recognize those that require review.

The process we described has simultaneously improved proposal quality, clarity of the role of the IRB, and support for DNP students. Because of the growth of DNP programs across the country, we offer this process as an innovative approach to the protection of human subjects and the education of students.

References

Baily, M.A., Bottrell, M., Lynn, J., Jennings B, & Hastings Center. (2006). The ethics of using QI methods to improve health care quality and safety. *Hastings Center Report 36,* S1-S40.

Brett, A., & Grodin, M. (1991). Ethical aspects of human experimentation in health services research. *Journal of the American Medical Association, 265,* 1854-1857.

Goldman, B., Dixon, L.B., Adler, D.A., Berlant, J., Dulit, R.A., Hackman, A., . . . Valenstein, M. (2010). Rational protection of subjects in research and quality improvement activities. *Psychiatric Services, 61,* 180-183.

Grady, C. (2007). Quality improvement and ethical oversight. *Annals of Internal Medicine, 146,* 680-681.

Ioannou, J.Z., & Dennison, C.R. (2010). Implementation of a specialized medical service to improve heart failure care and outcomes. *Heart & Lung, 39,* 355.

Kass, N.K., Pronovost, P.J., Sugarman, J., Groeschel, C.A., Lubomski, L.H., & Faden, R. (2008). Controversy and quality improvement: Lingering questions about ethics, oversight, and patient safety research. *The Joint Commission Journal on Quality and Patient Safety, 34,* 349-353.

Lo, B., & Groman, M. (2003). Oversight of quality improvement: Focusing on benefits and risks. *Archives of Internal Medicine. 163,* 1481-1486.

Lynn, J. (2004). When does quality improvement count as research? Human subject protection and theories of knowledge. *Quality and Safety in Health Care, 13,* 67-70.

Lynn, J., Baily, M.A., Bottrell M., Jennings, B., Levine, R.J., Davidoff, E., . . . James, B. (2007). The ethics of using quality improvement methods in health care. *Annals of Internal Medicine, 146,* 666-673.

Miller, F.G., & Emanuel, E.J. (2008). Quality-improvement research and informed consent. *New England Journal of Medicine, 358,* 765-767.

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979). *The Belmont report: Ethical principles and guidelines for the protection of human subjects of research.* Retrieved from http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

National Institutes of Health, Office for Protection From Research Risks. (1993). *Protecting human subjects: Institutional review board guidebook.* Washington, DC: U.S. Government Printing Office.

Pronovost, P., Needham, D., Berenholtz, S., Sinopoli, D., Chu, H., Cosgrove, S., . . . Goeschel, C. (2006). An intervention to decrease catheter-related bloodstream infection in the ICU. *New England Journal of Medicine, 355,* 2725-2732.

Raines, C.F. (2010, March 21). *The doctor of nursing practice: A report on progress* [PowerPoint® slides]. Retrieved from http://www.aacn.nche.edu/leading-initiatives/dnp/DNPForum3-10.pdf

Spencer, J. (2009). Reducing barriers and improving access to continence care: Examining the evidence. *Urologic Nursing, 29,* 405-413.

Taylor, H.A., Pronovost, P.J., Faden, R.R., Kass, N.E., & Sugarman, J. (2010). The ethical review of health care quality improvement initiatives: Findings from the field. *Issue Brief (Commonwealth Fund), 95,* 1-12.

U.S. Department of Health & Human Services, Office of Human Research Protection. (n.d.). *Quality improvement activities—FAQs.* Retrieved from http://answers.hhs.gov/ohrp/categories/1569