Academic and Institutional Review Board Collaboration to Ensure Ethical Conduct of Doctor of Nursing Practice Projects

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ABSTRACT

Background: Navigating the regulations to protect human subjects and private health information for Doctor of Nursing Practice (DNP) projects can be a formidable task for students, faculty, and the institutional review board (IRB). **Method:** Key stakeholders from the University of Iowa College of Nursing and the Human Subjects Office developed a standardized process for DNP students to follow, using a decision algorithm, a student orientation to the human subjects review process conducted by faculty and IRB chairs and staff, and a brief Human Subjects Research Determination form. **Results:** Over 2 years, 109 students completed the process, and 96.3% of their projects were deemed not to be human subjects research. Every student submitted documentation of adherence to the standardized process. Less time was spent by students, faculty, and the IRB in preparing and processing review requests. **Conclusion:** The interprofessional collaboration resulted in a streamlined process for the timely review of DNP projects. [*J Nurs Educ.* 2015;54(7):372-377.]

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According to the American Association of Colleges of Nursing (AACN, 2006), Doctor of Nursing Practice (DNP) projects may take different forms, including, but not limited to, integrated critical literature reviews, evidence-based practice (EBP) change initiatives, pilot studies, quality improvement (QI) projects, and practice portfolios. The AACN gives each member school the latitude to define DNP projects in terms that best incorporate the specialties offered by that school and the requirements of its degree-offering institution. Thus, DNP projects vary significantly and may or may not constitute human subjects research (HSR) or require access to protected health information (PHI). Regardless of the type of project, all students must receive a determination related to the protection of human subjects and health care information (Terry, 2012). When projects involve accessing PHI, even if they are not HSR, students need to comply with privacy and confidentiality requirements (Hockenberry, 2014; U.S. Department of Health and Human Services, n.d.b) and obtain permission from the appropriate institutional official. The purpose of this article is to describe the process and strategies that were developed at one institution to ensure regulatory compliance and the ethical conduct of all types of DNP projects.

The DNP program at the University of Iowa College of Nursing was initiated as a post-master's model in 2007. As the program transitioned to include a baccalaureate in nursing-to-DNP model in 2010, some challenges included the fact that more students were less likely to have had institutional review board (IRB) exposure; some faculty had minimal experience with IRB regulations and processes; other faculty had minimal experience in EBP and QI projects; and project settings, both within and outside of the university, academic medical center, or the state have or did not have their own IRBs. Therefore, to err on the side of ensuring compliance, many students were completing full IRB applications for projects that did not constitute HSR because of challenges differentiating between research, EBP, and QI. This resulted in unnecessary work for students, faculty, and IRB members and staff, as well as delays in project implementation and student progression. It became clear that the IRB processes could be improved to expedite the students' projects and relieve workload issues.

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TABLE 1

Categories of Doctor of Nursing Practice Projects

Category	Example
Projects using data (evidence) solely from the literature	Implementation of a legislative tracking tool for health care advocacy (Sheehan, 2010)
Development of evidence-based products	Development of an evidence-based guideline on hyaluronidase for the treatment of intravenous extravasations (Hanrahan, 2013)
Implementation of evidence-based practice changes	Reducing antibiotic overuse through implementation of a guideline on the management of acute otitis media (Coakley, 2014)
Quality improvement projects	Standardization of patient equipment throughout a health system to improve patient safety (Blackburn, 2014)
Human subjects research	Survey of children and adolescents to determine technology use and lifestyle habits (Ewald, 2013)

TABLE 2

Definitions of Terms Used to Classify Doctor of Nursing Practice Projects

Evidence-based practice is the integration of the best evidence available, with clinical expertise and patient values and preferences (Institute of Medicine, 2001; Sackett, Straus, Richardson, Rosenberg, & Haynes, 2000; Sigma Theta Tau International Honor Society of Nursing, 2005).

Quality improvement activities are "systematic, data-guided activities designed to bring about immediate, positive changes in the delivery of health care in particular settings" (Baily, Bottrell, Lynn, Jennings, & The Hastings Center, 2006, p. S5).

"Research is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" (#45CFR46.102[d]). "Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information" (#45CFR46.102[f]; U.S. Department of Health and Human Services, 2010).

PROCESS

DNP faculty met with the university's Associate Dean for Nursing Research to address challenges and concerns with the IRB process for DNP projects. The first step was to clarify the various types of DNP projects conducted by the students.

Types of DNP Projects

The authors reviewed students' DNP projects from the previous 6 years and classified them into five major categories: (a) projects that use data solely from the literature, such as systematic reviews, business plans, and health policy projects; (b) development of evidence-based products, such as clinical practice guidelines and decision tools; (c) implementation of evidence-based guidelines or other practice changes; (d) QI projects; and (e) projects that constitute HSR. Examples of DNP projects are provided in **Table 1**. The authors then applied the definitions of EBP, QI, and research (**Table 2**) to the projects and determined that the majority were either QI (approximately 75%) or EBP (approximately 20%), both of which are important foci in the authors' program and reflect their vision for DNP projects.

Clarifying the Scope of the Problem

Having documented that the majority of the DNP projects were not HSR, the authors partnered with stakeholders to develop an efficient process for differentiating QI and EBP projects from those that meet the federal definition of HSR. Stakeholders included DNP faculty, the Associate Dean for Nursing Research, three chairs of the university's IRBs, staff leadership from the Human Subjects Office, and a member of the University of Iowa Hospitals and Clinics Nursing Research and EBP Committee. The goal was to collaboratively develop a plan to ensure ethical conduct of all types of DNP projects.

Perspectives on the Problem. The collaboration began with each stakeholder identifying his or her concerns with the current process from his or her own perspective to determine common themes. The first common issue was around completion of the Human Subjects Research Determination form. Students electronically submitted the brief Human Subjects Research Determination request form describing the project, and the IRB chair or designee made a determination. If the IRB chair determined that a project met the definition of HSR, information from the short form was electronically transferred into a full IRB application. If the IRB chair determined that the project did not meet the definition of HSR, a memorandum documenting this determination was sent to the individual who submitted the request.

One issue arose from the Human Subjects Research Determination form itself. Students often misinterpreted questions about the potential generalizability of outcomes and the dissemination of results. The students, and sometimes the clinicians who conducted the EBP or QI projects, assumed that if

pre- or postperformance or outcomes of a practice change in a unit were measured, then it meant the project constituted generalizable research. Answering such questions incorrectly resulted in an automatic electronic transfer to an application for full IRB review.

A second issue concerned DNP project settings. Representatives from both the College of Nursing and the IRB noted that the process for ensuring human subjects' and personally identifiable data protection under two types of special circumstances could be enhanced. The first type of special circumstance is when the student conducts his or her project at an institution in which he or she is also employed. The second type is when the project is conducted outside the university (e.g., nonaffiliated clinic, hospital, school, or community setting).

Clarifications. Two outcomes were identified—the need for clarification of terms and the need for a process that would extend beyond the university setting to ensure that all DNP projects were ethically conducted, regardless of the type of project or setting.

Terms and definitions of projects were clarified (**Table 2**). For example, *generalizability* is a term that is often associated with research, as opposed to QI. Because QI projects are typically designed to be applicable only to a local situation and not to yield insights applicable to similar situations (Lynn et al., 2007), QI projects would not meet the Office of Human Research Protections' definition of being generalizable (U.S. Department of Health and Human Services, 2010). In addition, the DNP students at the authors' institution defend their projects via poster presentation and are encouraged to further disseminate the project by presenting it at conferences and publishing its outcomes. Consultation with the Office of Human Research Protections (L. Rooney, personal communication, November 5, 2012; U.S. Department of Health and Human Services, n.d.a) enabled agreement that conference presentations and publication of the project are not viewed as defining generalizability. Although journals often require documentation of an IRB's review of a project prior to acceptance of a manuscript for publication, even though the project may be one of QI, the memorandum generated after the IRB's Human Subjects Research Determination would provide such documentation that the students could use.

Special circumstances were also clarified. For example, if a DNP student is also an employee of the institution at which his or her project is being conducted, the Human Subjects Office expects the student to identify himself or herself as a student of the university and to obtain appropriate permissions to conduct the project as a part of his or her DNP education. These permissions may include letters of agreement from the appropriate site official and letters of compliance with institutional Health Insurance Portability and Accountability Act regulations.

In the second type of special circumstance, when a student conducts a project outside the university, the student must first determine whether there is an IRB that oversees activities at that setting. If there is an IRB, the student should first contact the DNP project site's IRB to ask whether the committee prefers to review the student's project or whether they defer to the university's IRB. This identifies the IRB of record and provides documentation of the agreement between institutions.

In both of these special circumstances, the university's Human Subjects Office staff works with individual DNP students to communicate with the project site's IRB.

STRATEGIES

Three strategies were identified to facilitate the review of DNP projects. First, the IRB chairs determined that questions related to QI projects should be added to the Human Subjects Research Determination form. Second, a decision algorithm, developed by the DNP faculty to summarize the process for students and faculty, was refined. Finally, an annual group IRB training session for DNP students was jointly planned and implemented by the staff of the Human Subjects Office, IRB chairs, and the DNP faculty.

Human Subjects Research Determination Form

The Human Subjects Research Determination form was revised, and new items were added to specifically address QI activities. If the project is not deemed HSR, the principal investigator (project director) receives a memorandum documenting this determination, as described above.

The University of Iowa DNP Project Decision Algorithm

In the early stages of defining the need for a process to ensure ethical conduct of all types of DNP projects, nursing faculty (J.M.F., V.C., J.K.W., A.M.M.) developed algorithms for how students would navigate the IRB system for the five different types of projects indicated previously. These faculty members used ongoing feedback from the group of stakeholders to incorporate five early algorithms into a single decision tool (The University of Iowa DNP Project Decision Algorithm) that would be applicable for all types of projects (**Figure**). As students navigate the process, related documents (**Table 3**) may be needed, contingent on the type of project being conducted.

All DNP students complete human subjects certification training during their coursework. After their project proposals have been approved by faculty, students follow the algorithm to ensure human subjects protection and patient privacy for their DNP projects.

The first step in any project that involves the collection or use of data from or about human subjects is to identify the IRB of record, based on the project setting. The next step is to determine whether the project constitutes HSR. If the project is deemed HSR, then IRB approval is required. If the project is deemed not HSR but the student will access PHI, permission must be obtained from an administrator or privacy officer at the project site. This also applies to non-HSR projects in external settings. Templates for these permissions create a standard process (**Table 3**).

Students using an external IRB also need to determine whether the project constitutes HSR by contacting that organization's IRB. If the project is deemed HSR, then IRB approval is required. Some IRBs do not have an intermediate step for HSR determination and require students to submit a full IRB application for review. A Reliance Agreement (**Table 3**) be-

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tween the external IRB and the university IRB is required if the project is federally funded.

Some projects require other considerations. For example, DNP students conducting HSR projects must also complete an electronic Conflict of Interest form (**Table 3**). Other individuals and committees may need to review the students' projects, regardless of the HSR determination.

The final step for all students is to complete a DNP Project/IRB Compliance Checklist and to obtain their advisor's signature. This form and all documents related to the IRB and accessing PHI are stored in their student file to document adherence to these processes. All requirements must be met before students can begin data collection or project implementation.

Joint DNP–IRB Training Session

The third strategy for facilitating review of DNP projects was a hands-on workshop for DNP students, which was jointly developed by the Human Subjects Office leadership, IRB chairs, and the DNP program leadership. The overall intent was for the DNP students to learn about compliance issues to conduct ethical projects, to gain a clear understanding of how to navigate the IRB system, and to discuss the uniqueness of their individual DNP projects with an IRB representative. The training session was held in a computer laboratory, where each participant logged into the university's IRB Web site. The session was held after students identified a project, submitted a written formal proposal, and received approval from their advisor and project chair. Students were expected to come prepared to discuss what their project would entail (e.g., data requirements and evaluation plan).

The 4-hour training session began with a series of presentations (**Table 4**) to orient DNP students to the regulatory requirements of HSR and to provide them time to ask questions that would help them to understand how to use the algorithm with their particular project. Specific presentations addressed how to complete the Human Subjects Research Determination form and the processes for contacting the external project site's IRB, if appropriate.

Following the formal presentations, the DNP students broke into two groups based on their need to use either the University of Iowa IRB or an external IRB. Each group worked with representatives from the Human Subjects Office and the College of Nursing faculty, who provided individualized hands-on assistance to ensure that each student understood the particular procedures they needed to follow.

OUTCOMES

The most beneficial overall outcome of the authors' collaboration is a streamlined process for the timely review of DNP projects. All three strategies resulted in positive outcomes, which are described below.

Human Subjects Research Determination Form

Because of the revised form, the DNP students' Human Subjects Research Determination applications reflect a better understanding of the process, and fewer students require one-to-one contact with the Human Subjects Office staff to request assistance in completing the form. Including language that is specific to QI projects has resulted in decreased confusion by both students and DNP faculty and decreased IRB workload.

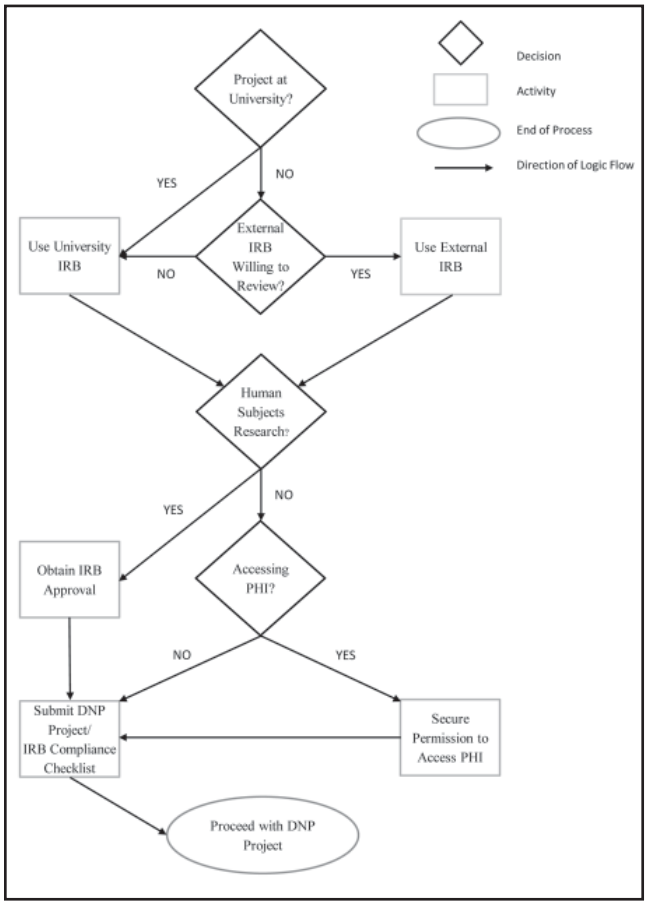

Figure. The University of Iowa Doctor of Nursing Practice (DNP) project decision algorithm. IRB = institutional review board; PHI = protected health information.

The University of Iowa DNP Project Decision Algorithm

The single-decision algorithm clearly and succinctly summarizes the sequential steps necessary to ensure human subjects protection and patient privacy for all types of DNP projects. The IRBs no longer receive applications for full review of projects that clearly do not constitute HSR. In addition, DNP students are able to obtain the necessary approvals efficiently and to submit documentation using the DNP Project–IRB Compliance Checklist. Project delays due to approval and documentation issues have been minimized.

Joint DNP–IRB Training Session

DNP students and faculty, as well as IRB chairs and staff, concur that the DNP–IRB workshop has been a success. Students seem less intimidated by the IRB process. Faculty members are more knowledgeable about navigating projects through the IRB and are better able to coach individual students through the process. IRB staff appreciate the ability to have a block of

TABLE 3

Relevant Documents for Doctor of Nursing Practice Projects, Depending on Project Type

Document	Description
Human Subjects Research Determination form	Electronic tool to assess whether a proposal constitutes human subjects research
Health Information Portability and Accountability Act letter templates	Templates for administrators or privacy officers to grant permission for students to access, secure, and maintain protected health information
Reliance Agreement form	Agreement between institutions, allowing a research protocol to undergo IRB review at the first institution and having the second institution waive review and accept the review of the lead institution
Conflict of Interest electronic form	Key personnel on human subjects applications complete an annual online disclosure form
Doctor of Nursing Practice Project–Institutional Review Board Compliance Checklist	Student documentation of compliance with protection of human subjects and protected health information requirements

TABLE 4

Doctor of Nursing Practice–Institutional Review Board Training Session Presentation Topics

Basic elements of human subjects research
Overview of IRB and federal guidelines
Health Information Portability and Accountability Act and protected health information
The University of Iowa DNP project decision algorithm
Introduction to the The University of Iowa Human Subjects Office electronic application system
Completing a Human Subjects Research Determination form
External IRBs and Reliance Agreement
Individual assistance by the Human Subjects Office and the College of Nursing

Note. DNP = Doctor of Nursing Practice; IRB = institutional review board.

time in which they can work with individual students to ensure compliance.

In 2013, 30 of 64 DNP students who were enrolled in the DNP Clinical Leadership Project course attended the initial joint DNP–IRB workshop. The remaining 34 students accessed the newly developed resources via the online course site. Eleven (17.2%) students conducting projects in 2013 used data from the literature only (e.g., developing evidence-based guidelines); therefore, their projects did not require IRB review. The remaining students obtained Human Subjects Research Determinations. Fifty (78.1%) additional students conducted projects that were deemed not HSR. Only three (4.7%) students' projects met the regulatory definition of HSR.

A posttraining survey was sent to workshop attendees to determine what did and what did not work well during the initial training session in 2013. Feedback from that session resulted in improvements to the second workshop session offered in 2014. Those improvements included asking the DNP students to be prepared to discuss specific information related to the DNP project they were planning and recording the session for those DNP students who were not on campus.

In 2014, 28 of 45 DNP students attended the joint DNP–IRB workshop, which was recorded. The other 17 students were able to access the session's recording and the updated resources. Two (4.4%) students used data from the literature only; therefore, their projects did not require review. The remaining students obtained Human Subjects Research Determinations. Forty-two (93.3%) additional students conducted projects that were deemed not HSR. Only one (2.2%) student's project met the regulatory definition of HSR.

DISCUSSION

The current article describes one institution's approach to ensuring ethical conduct and regulatory compliance for DNP projects. Since the inception of the DNP program, project coursework has been part of students' plans of study. According to the AACN's *The Essentials of Doctoral Education for Advanced Practice Nursing* (2006), "For practice doctorates, requiring a dissertation or other original research is contrary to the intent of the DNP" (p. 20). The DNP project is loosely defined, and the only requirement is that it be the "foundation for future scholarly practice" (AACN, 2006, p. 20). Since the development of the DNP *Essentials*, the challenge of defining and implementing DNP projects has been noted. Currently, an AACN DNP Implementation Task Force is charged with, among other things, providing clarity regarding the DNP scholarly project, and a white paper is planned for July 2015 release (AACN, 2014). Developing a realistic process for reviewing DNP projects to protect potential human subjects and PHI is essential for DNP programs to address.

Although the recent literature describes a process for IRB preapproval of DNP projects using a nursing faculty IRB liaison (Szanton, Taylor, & Terhaar, 2013), the process at the authors' institution includes interprofessional collaboration. Developing this process and implementing strategies for student education

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and the expedient application for Human Subjects Research Determination and IRB approval, if needed, would likely not have been possible without the active involvement of all stakeholders. Each stakeholder brought a unique perspective to be considered and provided valuable input to improve the process of IRB review.

The authors' program has been positively impacted by the successful implementation of the strategies described in this article. Both students and faculty now have a better understanding of the requirements for conducting ethical DNP projects. Unnecessary work for students, faculty, and IRB members has decreased, and overall satisfaction with the process is high. Because few of the students' projects are deemed HSR, the authors are confident that the projects are consistent with the intent of the AACN's DNP *Essentials* (2006). Finally, the IRB process now serves as a template that can be used by the academic medical center, other colleges within the authors' university, and other DNP programs.

The current project, like many of the students' projects, has been a QI endeavor. As a team, the authors will continue to evaluate both processes and outcomes to improve education, as well as the efficiency in ensuring ethical conduct of DNP projects. Future initiatives include prerecorded presentations, which students can view prior to the training session, to allow for more time for hands-on completion of the Human Subjects Research Determination forms, review of external IRB issues, and to answer individual questions.

REFERENCES

American Association of Colleges of Nursing. (2006). *The essentials of doctoral education for advanced practice nursing.* Retrieved from http://www.aacn.nche.edu/education-resources/essential-series

American Association of Colleges of Nursing. (2014). *DNP talking points.* Retrieved from http://www.aacn.nche.edu/dnp/about/talking-points

Baily, M.A., Bottrell, M., Lynn, J., Jennings, B., & The Hastings Center. (2006). The ethics of using QI methods to improve health care quality and safety [Special report]. *The Hastings Center Report, 36*(4), S1-S40. Retrieved from http://www.thehastingscenter.org/Publications/SpecialReports/Detail.aspx?id=1342

Blackburn, K. (2014). *Standardization of patient equipment: A quality improvement project* (Unpublished Doctor of Nursing Practice project). The University of Iowa College of Nursing, Iowa City, IA.

Coakley, T. (2014). *Reducing antibiotic overuse through implementation of an acute otitis media management guideline* (Unpublished Doctor of Nursing Practice project). The University of Iowa College of Nursing, Iowa City, IA.

Ewald, K. (2013). *Technology use in obese children and adolescents: A survey to determine lifestyle habits* (Unpublished Doctor of Nursing Practice project). The University of Iowa College of Nursing, Iowa City, IA.

Hanrahan, K. (2013). Hyaluronidase for treatment of intravenous extravasations: Implementation of an evidence-based guideline in a pediatric population. *Journal for Specialists in Pediatric Nursing, 18,* 253-262.

Hockenberry, M. (2014). Quality improvement and evidence-based practice change projects and the institutional review board: Is approval necessary? *Worldviews on Evidence-Based Nursing, 11,* 217-218.

Institute of Medicine. (2001). *Crossing the quality chasm: A new health system for the 21st century.* Washington, DC: National Academies Press.

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

Sackett, D.L., Straus, S.E., Richardson, W.S., Rosenberg, W., & Haynes, R.B. (2000). *Evidence-based medicine: How to practice and teach EBM* (2nd ed.). Edinburgh, UK: Churchill Livingstone.

Sheehan, A. (2010). The value of health care advocacy for nurse practitioners. *Journal of Pediatric Health Care, 24,* 280-282. doi:10.1016/j.pedhc.2010.04.001

Sigma Theta Tau International Honor Society of Nursing®. (2005). *Evidence-based nursing position statement.* Retrieved from http://www.nursingsociety.org/aboutus/PositionPapers/Pages/EBN_positionpaper.aspx

Szanton, S.L., Taylor, H.A., & Terhaar, M. (2013). Development of an institutional review board process for Doctor of Nursing Practice students: Process and outcome. *Journal of Nursing Education, 52,* 51-55. doi:10.3928/01484834-20121212-01

Terry, A.J. (2012). *Clinical research for the doctor of nursing practice.* Sudbury, MA: Jones & Bartlett.

U.S. Department of Health and Human Services. (n.d.a.). *Frequently asked questions about human research: Quality improvement activities FAQs.* Retrieved from http://answers.hhs.gov/ohrp/categories/1569

U.S. Department of Health and Human Services. (n.d.b.). *Health information privacy.* Retrieved from http://www.hhs.gov/ocr/privacy/index.html

U.S. Department of Health and Human Services. (2010). *Code of federal regulations.* Retrieved from http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html