CHAPTER THREE

The Institutional Review Board Process

Catherine Dearman, Jennifer Styron, and Sheila Whitworth

Chapter Objectives

1. Examine the process for initiating and completing the institutional review board (IRB) process—the when, why, and how to navigate the process.
2. Formulate a crosswalk that features the parts associated with initiating and completing the IRB process.

Key Terms

Human subject protection
Human subjects
Informed consent
Institutional review board (IRB)

Roles

Participant
Researcher
Reviewer

Professional Values

Beneficence
Quality
Respect for persons
Social justice

Core Competencies

Analysis
Communication
Design
Development

Introduction

This chapter reviews the role of the **institutional review board (IRB)** in an organization and describes the basic process used in the review of a study. The institutional review board is integral to the protection of **human subjects** and connecting those subjects to the protocols and safeguards included in completing an IRB application. Organizations sponsoring research and other scholarly work must consider the impact of that work on human subjects and be able to determine whether information gleaned from the work can be generalized to the

public. Therefore, IRB approval should be secured prior to any data collection for research and quality improvement projects.

The IRB comprises a representative group of faculty and staff within an institution who are experienced in research processes and thoroughly understand how the rights of subjects in the research are protected. The IRB reviews all research and many quality improvement protocols involving human subjects prior to their implementation, to assure that subjects' human rights are protected. In many cases, IRB approval is a basic requirement to publication of the findings, including those from quality improvement projects.

Inherent in the IRB review is the independent nature of the review and the reviewers—that is, researchers do not review their own work, but rather independent members of the IRB review each submission. In some cases, more than one IRB will need to be involved in the review of the research, especially if the university is not connected to the clinical facility where the research will occur.

Regardless of the project that is identified, the initial step is to complete a needs assessment, analyze the data, and assimilate data as background support when building the business case. However, one cannot dismiss the need to obtain IRB approval if the data or outcomes of a project will be disseminated beyond the immediate organization or system. Securing IRB approval at the beginning of the project limits future issues.

Historical Perspective Related to Protection of Human Subjects

The Federal Policy for the Protection of Human Subjects requires universities or other institutions that receive federal funds and conduct biomedical or behavioral research involving human subjects to establish an institutional review process. The "Common Rule," as the policy is widely known, requires a research institution to assure the protection of the human rights of human subjects who participate in research. The institution is bound by law, then, to assure that all researchers follow this rule with regard to selecting subjects and obtaining

informed consent from them (U.S. Department of Health and Human Services [DHHS], 2011, 2012).

IRBs emerged based on principles included in the Nuremberg Code, the Declaration of Helsinki (World Medical Association, 2008), and the Belmont Report. These documents define the minimum codes for conducting research with human beings, as well the ethical principles of beneficence, respect, and justice, which form the basis for all human research endeavors (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research [National Commission], 1979). The concept of beneficence assures that the study is structured in such a way that it will benefit—and not harm—the subjects. Researchers must then address the risks and benefits inherent in the research for all participants. Respect for persons and their right to choose to participate or not, as well as their right to cease participation at any point, is addressed through the informed consent process. Justice addresses the potential for all persons to be included in the study; no single person or group—and particularly not a vulnerable person or group—can be singled out to receive benefits or harm from the research (National Commission, 1979).

What is a human subject? Human subjects are living participants who are working with one or more researchers who are studying a phenomenon to acquire data by involvement (can be via distance; not required to be face-to-face) or data that can be used to distinguish one phenomenon from another.

The History of the Human Subjects Protection System

Human subject protection began with the *Nuremberg Code*, which was developed for the Nuremberg Military Tribunal as a standard against which to judge the human experimentation conducted by the Nazis during World War II. The Nuremberg Code captures many of what are now taken to be the basic principles governing the ethical conduct of research involving human subjects. Its first provision states that "the voluntary consent of the human subject is absolutely essential." Freely given consent to participate in research is the cornerstone of ethical experimentation involving human subjects. The Nuremberg Code also provides the details implied by such a requirement—namely, capacity

to consent, freedom from coercion, and comprehension of the risks and benefits involved. Other provisions require that risk and harm be minimized, that the risk/benefit ratio be determined and shared with the potential subjects of the research, that qualified investigators use appropriate research designs, and that subjects have the freedom to withdraw at any time.

Similar recommendations were made by the World Medical Association in its *Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects*, first adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, and subsequently revised by the 29th World Medical Assembly, Tokyo, Japan, 1975, and by the 41st World Medical Assembly, Hong Kong, 1989 (World Medical Association, 2008). The Declaration of Helsinki further distinguishes therapeutic from nontherapeutic research (Steneck, 2007).

In the United States, regulations protecting human subjects first became effective on May 30, 1974. These regulations were promulgated by the Department of Health, Education and Welfare (DHEW) and raised to regulatory status in 1966 as the National Institute of Health's (NIH) Policies for the Protection of Human Subjects. The regulations established the IRB as one mechanism through which human subjects could be protected.

In July 1974, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established. The Commission met from 1974 to 1978 and issued reports identifying the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and recommending guidelines to ensure that research is conducted in accordance with those principles. Its report setting forth the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects is titled *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. The Belmont Report, which is named after the Belmont Conference Center at the Smithsonian Institution, sets forth the basic ethical principles underlying the acceptable conduct of research involving human subjects. Those principles—respect for persons, beneficence, and justice—are now accepted as the three quintessential requirements for the ethical conduct of research involving human subjects and are discussed below (National Commission, 1979).

- *Respect for persons* involves a researcher and his or her team recognizing the personal dignity and autonomy of individuals, and providing for special protection of those persons with diminished autonomy.
- *Beneficence* entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm.
- *Justice* requires that the benefits and burdens of research be distributed fairly.

The Belmont Report also describes how these principles apply to the conduct of research. Specifically, the principle of respect for persons underlies the need to obtain informed consent; the principle of beneficence underlies the need to engage in a risk/benefit analysis and to minimize risks; and the principle of justice requires that subjects be fairly selected. As was mandated by the congressional charge to the National Commission, the Belmont Report also provides a distinction between "practice" and "research." The text of the Belmont Report is thus divided into two sections: (1) boundaries between practice and research, and (2) basic ethical principles (DHHS, 2010a).

The DHHS regulations are codified at Title 45 Part 46 of the Code of Federal Regulations and became final on January 16, 1981; these regulations were revised effective March 4, 1983, and June 18, 1991. The 1991 revision involved the adoption of the Federal Policy for the Protection of Human Subjects. The Federal Policy ("Common Rule") was promulgated by the 16 federal agencies that conduct, support, or otherwise regulate human-subjects research; the Food and Drug Administration (FDA) also adopted certain provisions. The Federal Policy is designed to make the human-subjects protection system uniform in all relevant federal agencies and departments. Additional protections for various vulnerable populations have been adopted by DHHS reflecting vulnerable populations such as pregnant women (August 8, 1975; revised January 11, 1978, and November 3, 1978), prisoners (November 16, 1978), and children (March 8, 1983, and revised June 18, 1991) (DHHS, 2010a).

An account of the history of human-subjects research and the human-subjects protection system in the United States can be found in Rothman's *Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision Making* and in Maloney's *Protection of Human Research*

Subjects. Rothman details the abuses to which human subjects were exposed, culminating in Beecher's 1966 article, "Ethics and Clinical Research," published in the *New England Journal of Medicine*, and ultimately contributing to the impetus for the first NIH and FDA regulations (Fain, 2009).

Definition of Research

Research is a "diligent and systematic inquiry or investigation into a subject in order to discover or revise facts, theories, applications . . . " (Dictionary.com, n.d.). The intent to publish findings is generally considered as contributing to generalizable knowledge. An investigation, then, must meet certain criteria to be classified as research. Research studies are designed in an organized, logical process that can support a range of goals, from basic scientific inquiry to a qualitative research study of a specified group. Research processes, measurement, assessment, and data collection are required elements of the study itself. Essentially, research is completed in a manner that will allow findings, experiences, or understandings gleaned from the work to be generalized to the broader population. Some research involves rodents, larger animals, or even primates. These studies are evaluated differently than research involving human subjects. When humans are involved, the research processes and procedures that include consent forms and the issue of informed consent must be evaluated by an IRB (DHHS, 2010b).

The research project is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective. The Belmont Report recognizes that "experimental" procedures do not necessarily constitute research, and that research and practice may occur simultaneously. It suggests that the safety and effectiveness of such "experimental" procedures should be investigated early, and that institutional oversight mechanisms, such as medical practice committees, can ensure that this need is met by requiring that "major innovation[s] be incorporated into a formal research project."

Boundaries Between Practice and Research

Why discuss IRB when quality improvement processes and quality assessments are the foci for most clinical nurse leaders (CNLs), nurse executives, doctor of

nursing practice (DNP) candidates, and other clinical doctorate students? If the IRB is predominantly focused on the ethical conduct of research, then why should quality improvement projects be reviewed by the IRB? After all, quality improvement is not research, is it? While recognizing that the distinction between research and therapy is often blurred, practice is described as interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice, then, is to provide diagnosis, preventive treatment, or therapy to particular individuals.

Ultimately, patients are the focus of quality improvement/process improvement projects, and their rights must be protected (Speers, 2008); the IRB process offers that protection. Similarly, community needs assessments can impact individuals and populations; thus, their protection is also warranted.

Quality improvement activities are widely regarded as critical to the effort to reduce healthcare errors and improve patient outcomes. Most can be readily distinguished from research; however, some cannot (Speers, 2008). The issue for students in nurse executive, clinical nurse leader, and DNP programs is that they are not generating new knowledge; instead, they are testing and offering translation of research findings into practice and the care of patients. To share with colleagues a project's success in improving quality of care, results are published, which brings quality improvement projects into the realm of research.

In 2007, national attention was brought to the impact of quality improvement studies on patient care. In turn, many healthcare professionals became involved in heated arguments about the differences between research and quality improvement. For example, a major care provider implemented a checklist for insertion of large intravenous lines in patients. As a part of this checklist, providers were reminded to wash their hands prior to the procedure and to wear sterile gloves and a gown. Within 3 months, IV line infection rates fell precipitously, resulting in a simultaneous reduction in costs for the provider. However, because the checklist was determined to be an intervention that impacted patients and no consent had been obtained from those patients, the Office of Human Research Protection closed down the program. This was done despite the benign nature of the intervention and the significantly positive outcomes realized for patients.

As a result of these events, more attention is now being paid to process and quality improvement projects and drives the review of projects by IRBs. The problem that most students and project managers face with regard to completion of the application to the IRB for projects is that the application uses research language, not quality improvement language. Students frequently attempt, in error, to reconcile quality improvement projects with research language, such as describing an experimental design when presenting an intervention.

The information that IRB members need with regard to quality improvement projects is generally confined to the "W" questions and answers: What will be done? Who will do it, and who will be involved in it? When will it be done (include stages)? Where will it be done, and how will it impact processes in the location(s)? Why is it necessary (include the potential impact on practice and improving health care)? In addition to these questions, the researcher/project manager needs to answer the "How" questions: How will the project unfold? How long will it take? How will the impact be measured? Clarity is essential in the application process; students and faculty should seek help on an as-needed basis.

Applying the Ethical Principles to Both Research and Quality Improvement

The responsible conduct of research (RCR) requires investigators involved in any level of the research to complete basic training in the protection of human subjects. Scholarship in the health sciences requires a clear understanding of the ethics involved in conducting research. This basic training can be obtained through the National Institutes of Health or the Collaborative Institutional Training Initiative (CITI) modules (CITI, 2011; NIH, 2011).

Respect for Persons

RCR training addresses the ethical principles of respect for persons. Informed consent to participate in research or a quality improvement project is required by the ethical principle of "respect for persons." It includes three elements: information, comprehension, and voluntariness.

First, potential subjects must be given sufficient information to be able to decide whether to participate, including the research procedures, their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. Incomplete disclosure is justified only if it is clear that (1) the goals of the research cannot be accomplished if full disclosure is made, (2) the undisclosed risks are minimal, and (3) when appropriate, subjects will be debriefed and provided with the research results.

Second, subjects must be able to comprehend the information that is given to them. The presentation of information must be adapted to the subject's capacity to understand it; researchers may be required to test potential subjects to assure they understand. Where persons with limited ability to comprehend are involved, they should be given the opportunity to choose whether to participate (to the extent they are able to do so), and their objections should not be overridden. Each such class of persons should be considered on its own terms (e.g., minors, persons with impaired mental capacities, the terminally ill, and the comatose).

Third, consent to participate must be voluntarily given. The conditions under which an agreement to participate is made must be free from coercion and undue influence. IRBs are especially sensitive to these factors when particularly vulnerable subjects are involved.

Beneficence

The principle of beneficence addresses risk/benefit assessments and includes information on the probability and potential magnitude of possible harms and benefits. Researchers must define the nature and scope of the risks and benefits, while systematically assessing them. All possible harms—not just physical or psychological pain or injury—should be considered. The principle of beneficence requires both protecting individual subjects against risk of harm and considering not only the benefits for the individual, but also the societal benefits that might be gained from the research.

Justice

The principle of justice mandates that the process used to select research subjects must be fair and must result in fair selection outcomes. The "justness" of subject selection relates both to the subject as an individual and to the subject as a member of social, racial, sexual, or ethnic groups.

With respect to their status as individuals, subjects should not be selected either because the researcher favors them or because they are held in disdain (involving "undesirable" persons in risky research). Further, "social justice" indicates an "order of preference in the selection of classes of subjects (adults before children) and that some classes of potential subjects (the institutionalized mentally infirm or prisoners) may be involved as research subjects, if at all, only on certain conditions" (DHHS, 1993).

Informed Consent

The process of assuring that the participants in research or quality improvement projects are aware of their rights and the three primary principles of respect for persons, beneficence, and justice is termed *informed consent*. Informed consent documents must present the information clearly and in readily understandable language without esoteric terms or convoluted sentence structure or word use.

The two primary elements to be addressed in the informed consent process are the provision of complete information about the study/project and the understanding of the participant regarding that information. Providing information alone is not sufficient to meet the standard of informed consent—the participant must also fully understand what he or she is agreeing to as a part of the study/project.

Some key elements of informed consent were discussed previously in relation to respect for persons, beneficence, and justice. However, some populations may be fully informed and voice understanding, yet not truly understand. Such may be the case with individuals with low literacy, for example. Options for assisting those with low literacy skills include reading the consent form for the participant and allowing sufficient time for the participant time to consult with another individual, such as a family member or clergy.

Another special case arises with children who participate in research/projects. Parents must provide consent for all minors participating in research. The children, too, must give permission (assent) to be involved in the study. In cases where higher risks are associated, the researcher may be required to obtain assent from the child and well as consent from both parents.

Typically, informed consent takes the form of a written, signed document. However, waiver of written informed consent can be approved if the presence of a signed document could increase the risk associated with participation. The waiver applies only to the written signed document; it does not apply for the actual process of informing the participants.

Institutional Review Board Processes and Procedures

Having to complete an IRB application can appear to be quite complicated and off-putting, but the process actually is straightforward and procedurally oriented. When one considers that the overall purpose of the IRB is to protect human subjects, the process becomes fairly benign.

IRB reviewers look for clear explanations of what will be done, who will do it, when it will be done, and how it will be done, so that the board members can determine if the project requires full board review or is eligible for expedited or exempt status. A clear understanding of the intent of the project is critical to the IRB review process. The discussion that follows highlights some ways to respond to the nature of the question without categorizing the quality improvement project in research terms while assuring ready understanding by IRB review teams. Some of the areas of the application are readily discernable, and others take a bit more information.

The remainder of this section provides details on the information needed to complete an IRB application. The basic processes the application will follow during the staged review are also addressed.

Research Purpose

Typically, the researcher needs to provide a brief description of the intent of the project. This section is basically the same for research studies or quality

improvement projects. The applicant needs to answer the question, What is the problem and which impacts will the proposed research/project have?

Subject or Population

Who will be involved in the project and how? To which population will the results be generalizable? Again, this section is the same for research studies or for quality improvement projects. Basically, the information presented must allow investigators, institutions, or IRBs to determine if the proposed methods of selecting participants could result in unjust distributions of the burdens and benefits of research. For example, subjects should not be selected simply because they are readily available in settings where research is conducted, or because they are "easy to manipulate as a result of their illness or socioeconomic condition" (DHHS, 1993).

Design of the Study

This section is very different for research studies and quality improvement projects. The applicant will need to provide enough information for reviewers to determine if the design fits the purpose and has the potential to yield the anticipated outcomes.

For research studies, the discussion of study design should address the overall nature of the study—experimental, quasi-experimental, descriptive, or something. Applicants must provide specific aims that the research will address and explain how the design will facilitate achieving those aims.

For quality improvement (QI) studies, the QI design, like the research design, must be linked to the project and to the project site. Some typical QI designs are the FADE model (focus, analyze, develop, and execute), PDSA (plan, do, study, act), and Six Sigma. Six Sigma actually encompasses two different models: DMAIC (define, measure, analyze, improve, control) and DMADV (define, measure, analyze, design, verify), which are used for existing and new processes, respectively. The basic premise is the same no matter which design is specified: Reviewers must know how the project will be conducted.

Privacy and Confidentiality

How will the researcher protect the information collected? Will participants be recognizable? Will responses be linked to participants? How and where will the data be stored? Who will have access? This last issue is particularly relevant to staff or patient participants who may fear retribution if they answer questions truthfully. In QI projects, participant pools are typically smaller and site-specific. The researcher must carefully assure that the privacy of all participants is protected.

Inclusion/Exclusion Criteria

How will the researcher determine eligibility of participants? The applicant must describe the processes and procedures used in determining who is eligible to participate in the research/project versus who is not eligible. The researcher will also need to assure that the issue of vulnerability is addressed. Frequently, quality improvement projects do not include children or other vulnerable populations, although that is not a hard-and-fast rule. Consequently, the researcher must describe inclusion and exclusion criteria comprehensively. If a population or subgroup is excluded for any reason, the application must clearly address those criteria. The researcher must be aware that the IRB application may require a stipulation whether or not any vulnerable population is included.

Risks and Benefits from Participation

Even if they are minimal, the researcher needs to address all risks and benefits to the participant, actual or potential, including physical and psychological risks and benefits, inconvenience, and loss of privacy. If subjects will be paid to participate in the research, the amount of payment and the restrictions on the payment need to be explained in detail. With regard to risks and benefits, more attention is generally paid to the risks than to the benefits. Therefore, the IRB members must independently assess the risk to the participants to determine if they agree with the risk assessment in the application. Additionally, the IRB must determine the type, probability, and extent of the risk as much as possible. It must determine if the researcher's estimates of harm or benefit to participants are reasonable, given the facts and results of other studies.

Five basic principles apply to risk/benefit assessment:

1. "Brutal or inhumane treatment of human subjects is never morally justified."
2. Risks should be minimized, including the avoidance of using human subjects if at all possible.
3. IRBs must be scrupulous in insisting on sufficient justification for research involving "significant risk of serious impairment" (direct benefit to the subject or "manifest voluntariness of the participation").
4. The appropriateness of involving vulnerable populations must be demonstrated.
5. The proposed informed consent process must thoroughly and completely disclose relevant risks and benefits (IRBNet, 2012).

Outcomes

The researcher must describe how the findings will be used. Are the findings sufficient to propose a change in policy or practice, or will more research be needed with different groups, under different circumstances, or some other criterion?

For QI projects, will the project potentially change practice? How might that change occur? Who will the change affect?

Informed Consent Form

A copy of the informed consent document is included in the packet provided to the IRB so that an assessment can be made with regard to the accuracy of information shared with participants and the reading level required to assure true understanding.

Levels of Institutional Review Board Reviews

The IRB has the authority to approve or not approve research and/or QI projects (Fain, 2009). IRB reviews occur on three distinct levels depending on the degree to which the study is considered to constitute potential harm or violation of one or more ethical principles. Those three levels are full review, expedited,

and exempt (Polit & Beck, 2012). An applicant can request a specific level of review, but the final decision regarding that level rests with the IRB staff and committee.

The full review process requires that a full IRB committee, including scientific, nonscientific, and community members, evaluate the study. All members of the IRB read, consider, and evaluate each study. Primary and secondary reviewers are stipulated to present the salient facts of the study to the full board, including all components of human-subject protection. The researcher maintains responsibility for the responsible conduct of research, even with a full board review. A full board review is typically reserved for studies with inherent risks to participants. Examples of studies that fit this criterion are those focused on sensitive topics such as race, ethnicity, and sexual behaviors; studies focused on vulnerable populations; and clinical trials, especially related to medication regimens.

Expedited reviews are reserved for studies in which "minimal" exposure to risk is projected. Minimal risk is defined as the participant being at no greater risk than he or she could encounter as a part of daily life. Expedited reviews are typically, conducted by one or two members of the IRB committee and are reported at the IRB meeting but not discussed there. Many QI projects qualify for an expedited review, as they constitute minimal risk to subjects.

An exempt review designation is typically reserved for studies where no human subjects are involved or for studies where there is no risk to humans. Typically, exempt studies include situations where subjects cannot be identified, secondary review of existing data, studies in which data are gathered through observation of public behavior, and anonymous surveys (DHHS, 2010a).

Summary

- This chapter has provided an overview of the role of the institutional review board (IRB) in an organization, a review of the basic processes involved in the review of a study, and methods involved in the protection of human subjects.
- The institutional review board is the primary mechanism used by institutions to assure the protection of human subjects through informed

consent, justice, beneficience, and respect for persons. The institutional review board also reviews quality improvement studies to assure that human subjects are protected.

- Researchers must be aware of the institutional review board policies within their institutions and be prepared to complete the processes to assure the protection of the persons involved in their research.

Reflection Questions

1. Which institutional criteria are used to review an IRB application?
2. What differentiates a quality improvement project from research?

References

Collaborative Institutional Training Initiative (CITI). (2011). CITI course in the responsible conduct of research. https://www.citiprogram.org/rcrpage.asp?language=english&affiliation=100

Dictionary.com. (n.d.). "Research" definition. Retrieved from http://www.dictionary.reference.com/browse/research?s=t

Fain, J. A. (2009). *Reading, understanding, and applying nursing research* (3rd ed.). Philadelphia, PA: F. A. Davis.

IRBNet. (2012). Innovative solutions for compliance and research management. https://www.irbnet.org

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. http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4178b_09_02_Belmont%20Report.pdf

National Institutes of Health (NIH), Office of Extramural Research. (2011). Protecting human research participants. http://phrp.nihtraining.cm/users/login.php

Polit, D. F., & Beck, C. T. (2012). *Nursing research: Generating and assessing evidence for nursing practice* (9th ed.). Philadelphia, PA: Lippincott Williams & Wilkins.

Speers, M. A. (2008). Editorial: Quality Improvement: Research or non-research? AAHRPP perspective. *Association for the Accreditation of Human Research Protection Programs, Advance, 5*(2), 1–2.

Steneck, N. H. (2007). *ORI: Introduction to responsible conduct of research*. U.S. Department of Health and Human Services. http://www.ori.hhs.gov/publications/ori_intro_text.shtml

U.S. Department of Health and Human Services (DHHS). (1993). Institutional Review Board Guidebook. http://www.hhs.gov/ohrp/archive/irb/irb_introduction.htm

U.S. Department of Health and Human Services (DHHS). (2010a). Code of federal regulations. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.html#46.102

U.S. Department of Health and Human Services (DHHS). (2010b). Guidance on IRB continuing review of research. http://www.hhs.gov/ohrp/policy/continuingreview2010.html

U.S. Department of Health and Human Services (DHHS). (2011). Information related to advanced notice of proposed rulemaking (ANPRM) for revisions to the Common Rule. http://www.hhs.gov/ohrp/humansubjects/anprm2011.page.html

U.S. Department of Health & Human Services (DHHS). (2012). The federal policy for human subject protections (The Common Rule). http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html

World Medical Association. (2008). World Medical Association Declaration of Helsinki: Ethical principles for medical research involving human subjects. http://www.wma.net/en/30publications/10policies/b3/index.html

Case Exemplar

■ CASE STUDY 1

The Role of Research in Policy Development

Jennifer Styron and Ronald A. Styron, Jr.

Two researchers were interested collecting data regarding the types of cyberbullying collegiate students experienced in high school (grades 9–12), the effects of cyberbullying, and those who tend to serve as cyberbullies. The project was two-pronged. Part I of this research project was intended to provide school administrators and educators with information that they would find useful when developing policies and practices surrounding the safe use of technology and peer bullying. Part II sought to collect data to determine the level of cyberbullying students experienced on campus, the means by which students dealt with such cyberbullying issues, and the level of student awareness regarding campus resources.

Reflection Questions

1. Based on the research proposed, would this study be best suited for exempt, expedited, or full IRB review?
2. Are there foreseeable risks to conducting the study? If so, does this violate the principle of beneficence?
3. Is there a risk of privacy/confidentiality breaches in the proposed research?

CASE STUDY 2

Evaluating Interprofessional Education

Sheila Whitworth and Jennifer Styron

The aim of this study was to explore key themes found through a year-long interprofessional clinical experience. Emerging themes from the program's evaluation were expected to provide insights into the development of leadership and competency skills of nurses, physician assistants, and medical students. Findings were to be utilized to make program improvements and provide insight into effective teaching and learning strategies specific to leadership and communication competency development in interprofessional clinical settings. Solicited students would include only the students who attended an interprofessional experience over the course of the project period (August 2013 through July 2014). This group included students from the physician assistant, medical, and nursing programs. Informed consent processes were followed, but no signed consent was obtained. The primary investigator provided each participant with a copy of the consent agreement. Voluntarily participating in the project implied participant consent.

Reflection Questions

1. Do studies that primarily focus on program evaluation need to go through the IRB process? Why or why not?
2. Is it acceptable to provide informed consent but not require a signature prior to participation in the study? Does this still adequately address respect for persons, beneficence, and justice?
3. Was the population solicited representative for the aims of the study?

CASE STUDY 3

Accelerated Nursing Program and Faculty Efficacy

Sheila Whitworth and Jennifer Styron

The purpose of this project was to identify best practices of accelerated nursing programs and the characteristics of faculty teaching in accelerated programs. This project addressed three research questions: (1) the efficacy of curricular design of accelerated programs; (2) the characteristics of faculty teaching in accelerated nursing programs and the differences, if any, in teaching methods when compared with those who teach in hybrid or traditional programs; and (3) best practices for the recruitment of future faculty. Findings from this study provided insight into accelerated program development and curriculum that will further address the national issue of healthcare professional shortages and the need for highly educated nurses and nursing faculty.

Using a mixed-method design, project leads developed two quantitative instruments and conducted a regional pilot study to accelerated prelicensure programs that were institution members of the Southern Regional Education Board (SREB). This allowed the project team to understand programmatic models, faculty attributes, and resources and support needed for accelerated faculty. In total, 62 institution members with accelerated prelicensure programs, including 40 institution members with baccalaureate programs and 22 institution members with master's accelerated programs, were available for participation. In addition, solicitation for participation included faculty from the selected sample teaching in traditional or hybrid programs.

Reflection Questions

1. Would this proposal be considered research or quality improvement?
2. Were the inclusion/exclusion criteria utilized for this proposed research appropriate?
3. Did the proposed outcomes substantiate the need for this study?

CASE STUDY 4

The CNL Capstone Project: An Experiential and Transformative Process

Theodora Ledford

Differentiating quality projects from research often challenges students to ensure that the objective of the project is met and any impact on human subjects' protection is determined. Upon completing a microsystem needs assessment and engaging in dialogue with the institutional review board, it was established that the clinical nurse leader (CNL) project was needed to obtain information that supported nursing quality improvement data. Data gleaned from the project would be useful for detecting trends in and patterns of performance that affected more than the identified microsystem. Data collected would be utilized in the development of action plans in collaboration with other practice committees concerning nurse-sensitive indicators directed at quality, safe, and efficient patient outcomes. Additionally, data could engender interprofessional collaboration, opportunities to monitor and evaluate compliance with standards, recommendations to enhance continuous quality improvements, and the spread of safety initiatives throughout the healthcare system.

While the capstone project started initially as an outcomes-based endeavor where differentiating quality improvement from research was of foremost importance, the transformative processes that followed were valuable. The experience culminated in thoughts of how unit-based quality nursing councils could use data to create more solid structures and processes. As a result, an innovative environment was envisioned where strong professional practice would flourish and the mission, vision, and values would come to life. This notion can become a reality. However, during dialogue with colleagues and quality improvement staff, a fundamental action was needed—namely, the development of a guide for other nurses to understand the differences between quality improvement projects and research and the steps necessary for accomplishing meaningful and value-added quality projects that are patient-centric and advance care delivery. Steps are in process for the action to become reality.

Reflection Questions

1. Which individual challenges do students confront when completing IRB applications for universities and clinical agencies?
2. How might students create opportunities from challenges associated with quality improvement and research endeavors?