Ethical Principles of Informed Consent: Exploring Nurses’ Dual Role of Care Provider and Researcher

Tanya M. Judkins-Cohn, MSN, MEd, RN, Kiersten Kielwasser-Withrow, RNC-OB, MSN, CBE, Melissa Owen, MSN, CCTC, RN, and Jessica Ward, MPH, MSN, CPNP

Abstract

This article describes the ethical principles of autonomy, beneficence, and justice within the nurse researcher-participant relationship as these principles relate to the informed consent process for research. Within this process, the nurse is confronted with a dual role. This article describes how nurses, who are in the dual role of care provider and researcher, can apply these ethical principles to their practice in conjunction with the American Nurses Association’s code of ethics for nurses. This article also describes, as an element of ethical practice, the importance of using participant-centered quality measures to aid informed decision making of participants in research. In addition, the article provides strategies for improving the informed consent process in nursing research. Finally, case scenarios are discussed, along with the application of ethical principles within the awareness of the dual role of the nurse as care provider and researcher.


During the past two decades there has been an increase in strategies for fostering research and evidence-based nursing practice in the clinical setting (Chan, Gardner, Webster, & Geary, 2010). With the increase in research activities in the clinical setting, more nurses are engaging in research studies as principal investigators or research team members. The second most frequently reported primary nursing focus for doctorally prepared nurses is research, and 47.8% of nurses who report their principal nursing position as researcher are prepared at the bachelor’s degree level (Health Resources and Services Administration, 2010). This increase is also influenced by such initiatives as accomplishing and maintaining nursing excellence through the Magnet Recognition Program®. Furthermore, the 2010 Institute of Medicine’s Future of Nursing report recommended that by 2020 there will be a need for double the current number of doctorally prepared nurses, which is now reported to be fewer than 1% of all nurses (Institute of Medicine, 2010). The result is the creation of the dual role of care provider and researcher. This dual nursing role bears significant responsibility and demands a thorough understanding of the informed consent process in research. This includes having an understanding of the institutional review board process and the requirements for informed consent.

Following ethical informed consent procedures requires nurses to advocate for participants’ best in-
terests, ensures participants’ understanding of the informed consent process and the research study, and upholds the ethical principles of autonomy, beneficence, and justice. To adhere to the ethical principles of informed consent in research, the nurse must maintain a balance between clinical and research responsibilities, demonstrating the ability to differentiate between the nurse–patient and the researcher–participant relationships. This article explores the interplay of the ethical principles of autonomy, beneficence, and justice within the nurse–participant relationship and the relationship of these principles to the research informed consent process. Methods to enhance participants’ understanding of the informed consent process as well as the use of quality measures for informed consent and recommendations for continuing education are also discussed. In addition, two case scenarios are included to highlight the considerations of the dual role of care provider and researcher, along with recommendations for upholding the Belmont principles (U.S. Department of Health and Human Services [HHS], 1979).

**HISTORY OF INFORMED CONSENT IN RESEARCH**

In the 1930s and 1940s, unethical medical experiments were conducted without participant consent and without regard for the risk-benefit ratio. As a result, in 1946, physicians were prosecuted during the Doctors Trial at Nuremberg, and the Nuremberg Code was created (Nuremberg Code, 1949). The Nuremberg Code initiated the requirement of voluntary consent based on information about the research study, its risks, and the potential benefits as essential to research (Nuremberg Code, 1949). In 1964, the Declaration of Helsinki was developed by the World Medical Association as a set of ethical guidelines for researchers, including a provision for informed consent (Rickham, 1964). Yet, between 1932 and 1972, the Tuskegee Syphilis study was under way in the United States in which low-income African American males were monitored during 40 years without therapy for syphilis, even after a successful treatment was discovered (Tuskegee Syphilis Study Ad Hoc Advisory Panel, 1973). At least 28 and possibly more than 100 participants died as a result of advanced syphilitic lesions (Brandt, 1978; Peters, Peers, Olansky, Cutler, & Gleeson, 1955). Thus, in 1974, the National Research Act was passed, and subsequently the Belmont Report was published. The three principles of the Belmont Report (HHS, 1979)—respect for persons, beneficence, and justice—and their applications are shown in **Table 1**. These three principles are not only necessary elements of the informed consent process in research but also the foundation of the institutional review board review process.

**ETHICAL PRINCIPLES OF INFORMED CONSENT IN RESEARCH**

Informed consent is a process that protects human subjects and allows for voluntary, autonomous authorization by individuals who participate in clinical research. Research informed consent consists of disclosure, capacity, comprehension, and voluntary and autonomous permission. The basic elements of informed consent, as defined by HHS policy 46.116 (1998), are shown in **Table 2**. In addition, institutional review boards are tasked with evaluating the informed consent document and the process for these basic elements, along with the ethical conduct of the research study.

Informed consent has two main objectives—to respect and promote participants’ autonomy and to protect them from potential harm (Jefford & Moore, 2008). The foundation for both of these objectives lies in the Belmont principles of autonomy (respect for persons) and beneficence. Autonomy of participants requires that individuals are able to provide voluntary and informed consent before enrolling in a research study (HHS, 1979). If a participant is unable to provide voluntary

---

**Table 1**

<table>
<thead>
<tr>
<th>Principle</th>
<th>Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respect for persons: Individuals should be treated as autonomous, and those with diminished autonomy have the right to protection.</td>
<td>Access to participants; informed consent process</td>
</tr>
<tr>
<td>Beneficence: Researchers are to uphold the practice of doing no harm along with maximizing possible benefits and minimizing possible risks.</td>
<td>Assessment of risks and benefits</td>
</tr>
<tr>
<td>Justice: Researchers must select participants in a fair manner where there is an even distribution of benefits and risks.</td>
<td>Access and selection of participants</td>
</tr>
</tbody>
</table>

*Note. Data are from Greaney et al. (2012) and U.S. Department of Health and Human Services (1979).*
and informed consent, an alternative means should be explored and the participant should be provided with documented procedures for third-party consent (Greaney et al., 2012). Respect for persons also requires that during the informed consent process there is full disclosure of the nature of the research, the process, and the possibility of withdrawal from the study as well as the measures taken to maintain privacy of the participant (Greaney et al., 2012). Maximizing the possible benefits while minimizing possible harm to the research participants requires that researchers maintain the principles of beneficence and nonmaleficence (HHS, 1979).

While maintaining beneficence, researchers must be attuned to the pitfalls of the informed consent process, such as psychological distress and therapeutic misconception (Greaney et al., 2012). During the informed consent process, the nurse researcher must explore the possibility of participant psychological distress as a result of concerns that care may be affected by the decision not to participate. Beneficence can also be affected by therapeutic misconception in which the patient may, perhaps incorrectly, overestimate the perceived benefit of participation in the research study (Fried, 2001; Greaney et al., 2012). Exacerbation of therapeutic misconception may occur in scenarios in which the researcher functions in the role of care provider and the patient may misconstrue the personal benefits of research participation based on a preexisting trusting relationship with the nurse researcher (Greaney et al., 2012). The nurse researcher must make a clear distinction between the possibility of direct benefit as a result of study participation versus the lack of direct benefit but potential for new knowledge to improve future patient care. Furthermore, the nurse researcher must also explain that the research study is voluntary and that participation has no effect on the care being received.

**TABLE 2**

<table>
<thead>
<tr>
<th>BASIC ELEMENTS OF INFORMED CONSENT IN RESEARCH</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. An explanation of the purpose of the study, the study procedure, and the duration of the individual’s participation</td>
</tr>
<tr>
<td>2. A description of reasonably foreseeable risks to the participant</td>
</tr>
<tr>
<td>3. Reasonably expected benefits to the participant and others</td>
</tr>
<tr>
<td>4. Disclosure of treatment alternatives</td>
</tr>
<tr>
<td>5. A description of the extent to which confidentiality will be maintained</td>
</tr>
<tr>
<td>6. An explanation of compensation and a description of the availability of medical treatments if more than minimal risk is involved</td>
</tr>
<tr>
<td>7. An explanation of whom to contact with questions about the research or participants’ rights and in the event of a research-related injury</td>
</tr>
<tr>
<td>8. A statement about the voluntary nature of participation and the participant’s right to refuse to participate or discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled</td>
</tr>
</tbody>
</table>

*Note. Data from U.S. Department of Health and Human Services (1998).*

...
nurse researcher (Houghton, Casey, Shaw, & Murphy, 2010). This duality emanates from the duty to care and advocate for the patient balanced with the duty to maintain the integrity of the research. Nurse researchers must clearly delineate the distinction between therapeutic services and research activities to avoid any misinterpretation on the part of the potential participant (Larsen & McMillin, 2011).

**ETHICAL PRINCIPLES OF INFORMED CONSENT: ACKNOWLEDGING THE NURSE–PATIENT RELATIONSHIP**

The principle of respect for persons has two separate requirements: the requirement to acknowledge and promote autonomy and the requirement to protect individuals with diminished autonomy (Vreeman, Nyandiko, & Meslin, 2009). Enabling free and uncoerced participation in research is essential to preserve the requirement of respect for persons and to prevent harm within nursing research. Examples of such harm include exploitation, oppression, coercion, deception, betrayal, and discrimination. Furthermore, dissent or refusal to participate in a research study must be a real option for potential participants, one that carries no adverse consequences (Participants in the 2001 Conference on Ethical Aspects of Research in Developing Countries, 2004).

Disclosure of information, decisional capacity, and voluntarism are elements of informed consent that warrant particular attention in nursing research (Dimsdale, 2006). Awareness of the responsibility to protect vulnerable populations is inherent in the role of nurse researcher. Protection of vulnerable individuals begins with the assessment of decisional capacity and the implementation of appropriate provisions for informed consent. These provisions include presenting verbal and written information about the study in a manner that matches the literacy level of the participant, with adequate time for reiteration, questions, and clarification.

Voluntarism is a principle of informed consent that is closely related to decisional capacity and is defined by the extent to which an individual can act based on free will (Banner & Zimmer, 2012). Development, culture, environment, and illness are factors that may affect the voluntary nature of informed consent.

Nurse researchers also must consider power relationships that may affect the ability of a potential participant to dissent or consent, based on free will. Patients may feel obligated to consent to study participation out of fear that their clinical care may be adversely affected by dissent, particularly if the nurse researcher has a direct role in clinical care. Reducing the power imbalance and maintaining autonomy, thereby protecting against unintentional coercion, is the responsibility of the nurse researcher.

Within research, beneficence is an obligation that includes protecting participants from risks and unnecessary harm that may result from participation and respecting decisions made by potential participants. In accordance with the principle of beneficence, disclosure of potential benefits and risks is an essential component of the informed consent process. Specifically, the nurse researcher must provide the patient participant with information about how the study will be conducted, the actions that will be taken to reduce risks as much as possible, and the measures to protect the participant’s rights (Sims, 2010). The nurse researcher and the patient participant must decide when it is justifiable to seek and accept certain benefits associated with study participation despite the risk involved and when to forgo potential benefits because of the risks. The principle of beneficence takes on greater importance during the informed consent process when more than minimal risk is involved in the research study.

Trust is a key element of nurse–patient and researcher–participant relationships. Trust is also a key aspect of justice. Justice, the third Belmont principle, mainly applies to study design and the implementation and selection of participants but relates as well to informed consent in nursing research. Benefits and burdens of nursing research are distributed to participants and must be sufficiently disclosed through informed consent (Greaney et al., 2012). Much of nursing research involves the use of a convenience sample that may consist of the researcher’s primary patient population (Polit & Beck, 2008). It is therefore essential for nurse researchers to disclose information about participant selection and to explain that clinical care will not be affected if the patient declines to participate. High-quality informed consent in nursing research is achieved only when nurse researchers recognize each Belmont principle (HHS, 1979) and maintain these principles throughout the process of informed consent. Thus, the ability to measure and employ strategies to maintain quality informed consent is a necessary step in nursing research.

**MEASURES AND STRATEGIES TO IMPROVE THE QUALITY OF INFORMED CONSENT IN NURSING RESEARCH**

Both quantitative and qualitative approaches have been used to assess the quality of informed consent. Findings from these studies have identified that research participants may have a knowledge and comprehension deficit at various points. For example, Sugarman et al. (2005) designed and tested the Brief Informed Consent
Evaluation Protocol, an informed consent quality measure that yields a score for general understanding and a score for misunderstanding of the benefit to oneself. In this study of 632 clinical trial participants, 80% understood the research-based intention of the study. However, only 55% understood that study withdrawal was an option. By comparison, the Quality of Informed Consent instrument measures objective and subjective understanding of informed consent (Joffe, Cook, Cleary, Clark, & Weeks, 2001). Evaluation, using the Quality of Informed Consent instrument, suggested that clinical trial participants believed that their subjective understanding of essential elements of informed consent was sufficient, but they lacked understanding of the key elements of clinical trials and informed consent (Joffe et al., 2001). Another tool is the Process and Quality of Informed Consent, which is an observational instrument that identifies essential informational elements of informed consent and characterizes elements of communication processes in informed consent (Cohn, Jia, Smith, Erwin, & Larson, 2011). The instrument was designed based on the assertion that informed consent exists at the intersection of accurate factual information and effective communication. Initial feasibility testing showed that informed consent scenarios that combine accurate information with effective communication generate higher Process and Quality of Informed Consent scores (Cohn et al., 2011).

Finally, Tomlin, Desalis, Toerien, and Donovan (2012) performed a qualitative analysis to explore the views of nurses recruiting patients to participate in randomized controlled trials and to examine the extent to which informed consent practices were patient centered and followed essential informed consent principles. Content and thematic analyses showed that the nurses viewed themselves as clinicians and patient advocates rather than as recruiters. However, a significant subset of nurse–patient interactions constrained patient empowerment, thereby reducing the quality of informed consent in the encounters sampled. Extracts showed patterns of interruption, digression, inattentiveness to patient emotions, and incomplete information regarding the randomized controlled trial (Tomlin et al., 2012). The results of this study warrant further consideration, specifically, the dual role of the nurse researcher as related to the preservation of quality of informed consent.

To improve the overall quality of the informed consent process, comprehension must be assessed. Recall testing, proximity testing, and teach-back methods have shown some success and merit discussion (Kripalani, Bengtzen, Henderson, & Jacobson, 2008; Miller et al., 2007). Recall testing for comprehension occurs immediately after the entire informed consent encounter (Miller et al., 2007). Alternatively, the proximity testing method entails an assessment of comprehension of informed consent after the completion of each major section of the informed consent process. In a study comparing the efficacy of these methods, potential participants in the proximal testing group obtained significantly higher overall comprehension scores and scores specifically related to study risks and the voluntary nature of study participation (Miller et al., 2007). The third method, teach-back, incorporates open-ended questions throughout the informed consent process (Kripalani et al., 2008). This method involves asking potential participants to describe their understanding of elements of information explained during the informed consent process, such as the purpose of the study, potential risks and benefits, and study procedures. Other elements of informed consent that can be difficult to convey, such as freedom to withdraw, the voluntary nature of participation, and randomization, may be clarified with the teach-back method (Kripalani et al., 2008). The recall testing, proximity testing, and teach-back methods allow nurse researchers to assess comprehension of informed consent in real time. Additional opportunities are created for clarification and reiteration of complex concepts with the use of these methods in nursing research, thereby improving the overall quality of informed consent.

IMPLICATIONS FOR NURSING RESEARCH

Ethical issues are critical to the practice of nursing research and clinical nursing. Nurses function as patient advocates, and this role places them in an ideal position to ensure that research is conducted in an “ethical, scientifically valid manner” (Connelly, 2009, p. 386). By understanding patients’ clinical needs, nurses can effectively balance the three basic Belmont principles (beneficence, autonomy, and justice; HHS, 1979). The following practical guidelines may assist nurse researchers when obtaining informed consent (Connelly, 2009):

- Clearly describe the dual role assumed by the nurse in clinical care and research to the patient participant, if applicable.
- Maintain boundaries between the clinical and research roles.
- Avoid causing additional stress to the patient participant.
- Collaborate with the patient participant; avoid coercion.
- Maintain patient participant safety.
- Advocate for the patient participant.
- Notify the appropriate individuals of ethical concerns.
Nurse researchers must be adequately prepared through formal education in nursing research. This education should include specific elements of the nurse’s role in research, explanation of the informed consent process, and methods to enhance the quality of the process. Furthermore, nurse researchers must implement an informed consent process that places participants at the center. Participant-centered informed consent must be voluntary and without coercion, given that the participant participant has full comprehension of what is involved (Cohn, 2012).

Tomlin et al. (2012) reported that although nurse researchers primarily identify themselves as clinicians, ethical standards of informed consent processes are inconsistently upheld. Mindful interactional practices, participant-centered communication methods, and accurate and complete presentation of study details must be elements of every informed consent procedure executed by nurse researchers (Tomlin et al., 2012). To create an informed consent setting that is conducive to patient autonomy, it is important for nurse researchers to avoid interactional practices such as digression, inattentiveness to patient preferences and feelings, and interruption. Presentation of complete and accurate information about the research study itself is crucial to foster good patient decision-making.

Determining the type of communication style and the level of information preferred by the client is a necessary first step in quality informed consent (Banner & Zimmer, 2012). It is critical for the nurse researcher with concurrent clinical responsibilities to emphasize that the decision to participate in or withdraw from the study has no influence on clinical care. Furthermore, nurse researchers should consider using empirical measures to evaluate the quality of informed consent when conducting quantitative and qualitative research. Incorporating the results of measures of the quality of informed consent may assist nurse researchers in upholding ethical standards of informed consent in future research endeavors. The Brief Informed Consent Evaluation Protocol and the Quality of Informed Consent instrument may be implemented concurrently with qualitative or quantitative nursing research studies to gather information on the subjective and objective understanding of potential research participants (Joffe et al., 2001; Sugarman et al., 2005).

Cohn et al. (2011) asserted that quality informed consent exists at the intersection of effective communication and the presentation of accurate and factual information. The Process and Quality of Informed Consent tool may be particularly useful for nurse researchers because it yields results on the quality of both communication and the informational elements of informed consent (Cohn et al., 2011). If specific tools are not initiated as part of the research process, nurse researchers should, at a minimum, document measures taken to ensure understanding, including details of how risks and benefits were explained and questions raised by participants. This allows for an interactive exchange between the nurse researcher and the participant and establishes an informed process of providing consent beyond the signed informed consent document.

**IMPLICATIONS FOR CONTINUING EDUCATION IN NURSING**

As more clinical nurses assume the researcher role, research education should be interwoven within the nursing school curriculum and continuing education for nurses. The 2010 Institute of Medicine’s *Future of Nursing* report specified that nurses now need to attain competencies that support the delivery of high-quality care that includes research and evidence-based practice (Institute of Medicine, 2010). This entails expanding beyond memorization of concepts such as the Belmont Report (HHS, 1979) and advocates application of these principles within a clinical setting, as illustrated in the following case scenarios.

**Case Scenario 1**

S.H. is a direct patient care nurse in the intensive care unit of a community hospital as well as a member of her unit-based practice council. She recently started a doctor of nursing practice program that will require her to complete a clinical research study. She is interested in studying the effects of earplugs on reducing the incidence of intensive care unit delirium and increasing positive sleep perception. She has decided on a randomized controlled trial with two groups—those who receive earplugs at night for sleep and those who do not receive earplugs at night for sleep.

When considering the informed consent process, S.H. would need to take into account her roles as direct patient care provider and researcher. To ensure full and complete disclosure, she would need to identify herself as a researcher and a nurse when approaching potential patients as participants. When introducing the research and engaging potential study participants, S.H. would focus on the nature of the research, the voluntary nature of the study, the ability to withdraw at any time, and the privacy of the patient. This would include clearly explaining to patients that their care would not change regardless of whether they decide to participate in the research. Particular to this study and the two groups involved, those who receive earplugs and those who do not, S.H. must...
consider the possibility of therapeutic misconception. This can be avoided by providing adequate information and using an assessment of the quality of informed consent (Table 2). Ignoring the required steps may place participants in harm’s way. S.H. owes it to the participants to become knowledgeable about the process and to take steps to prevent any misunderstandings.

Case Scenario 2

C.P. is a direct patient care nurse in the medical-surgical unit of a community hospital. Recently her unit has had an influx of geriatric patients. During her shifts, she has noticed that her patients have complained of less pain and discomfort when she takes the time to just sit with them and be present. As a result, C.P. is thinking about developing a research study to explore the phenomenon of caring experiences in geriatric patients. To explore this idea, she has decided to develop a qualitative research study that will include audiorecorded interviews with geriatric patients admitted to her unit.

Like S.H., C.P. would need to be conscientious about her dual role as care provider and researcher when obtaining informed consent from potential study participants. C.P. will also need to be certain to explain the voluntary nature of the research study and to inform patients that participating or not participating will not affect the care received. During the informed consent process, C.H. will need to state clearly the risks of confidentiality and privacy related to audiorecorded interviews. In addition, she must address how she will reduce these risks and explain whether there is any benefit from participating in the study or if the benefit would be for future patients.

Regardless of the study design, it is imperative for C.P., as a nurse researcher, to adhere to a clearly delineated process that identifies the dual role. The nurse must be conscientious about maintaining the necessary boundaries to avoid added stress or feelings of coercion on the part of the patient. The nurse must be attentive to this nurse–patient relationship and maintain clarity throughout the informed consent process through engaging and effective conversation. If C.P. decides that the time and effort required for an effective informed consent process is not realistic and skips steps along the way, the participants are placed at risk. To avoid undue risk to participants, C.P. must understand that this process is designed to prevent harm associated with the dual role.

An understanding can be achieved through proper education in the Belmont principles (HHS, 1979), reinforcement of the nursing code of ethics (ANA, 2001), and adherence to a patient-centered approach to the informed consent process. In addition, by integrating the ethics of informed consent in research into nursing competencies, nurse educators and nurse leaders improve the quality of the nursing work force. If both S.H. and C.P. follow the proposed guidelines, they can both advocate for clients and protect them.

CONCLUSION

The ethical issues associated with the nurse acting as both care provider and researcher present a teaching opportunity in nursing schools and an opportunity for a necessary discussion within the nursing profession. As more nurses begin to function as principal or co-investigators of research studies, understanding how the duality of their roles influences the informed consent process will continue to be an ethical focal point in nursing research (Sidebar). It is the responsibility of the nurse researcher to distinguish between the nurse–patient and researcher–participant relationships. This includes understanding the difference between the goals of clinical care and research, following the research-specific ethics involved in the informed consent process, and incorporating strategies and measurement instruments for the quality of informed consent.

REFERENCES


Chan, R., Gardner, G., Webster, J., & Geary, A. (2010). Building re-


Copyright © SLACK Incorporated