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Science, Technology, and Innovation: Nursing Responsibilities in Clinical Research

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Introduction

Clinical research is a systematic investigation of human biology, health, or illness, involving human beings.[1] The goal of clinical research is to develop or contribute to generalizable knowledge about human health and illness and to test methods that might improve our ability to prevent, diagnose, and treat illness and provide care for patients. Clinical research is built on laboratory and animal studies (pre-clinical) and often involves clinical trials, which are specifically designed to test the safety and efficacy of interventions in humans. Carefully conducted clinical trials are considered the most reliable way to determine whether therapeutic or preventive interventions are safe and effective for diseases like cancer, HIV/AIDS, and asthma. There are five types of clinical trials including (a) treatment, (b) prevention, (c) diagnostic, (d) screening, and (e) quality of life, which are defined in Table 1.

The benefits of clinical research for society have been significant, yet controversy surrounding it continues to pose profound ethical questions. Nurses are critical to the conduct of ethical clinical research and are involved in research through diverse roles steeped with clinical, ethical, and regulatory challenges. As the volume, diversity, and complexity of clinical research escalates, the challenges that nurses encounter associated with the ethical conduct of research have intensified. Examining, understanding, and addressing the unique and complex ethical challenges that face nurses in their various clinical research roles is integral to upholding the moral commitment that nurses make to patients, including protecting their rights and ensuring their safety.

Nurses involved in research, whether as a principal investigator, a study coordinator, clinical trials nurse, or as a staff nurse caring for patients who are research subjects have a responsibility

to promote the ethical conduct of clinical research. Fulfilling this responsibility requires understanding what clinical research is and knowing what makes clinical research ethical. Only then can a nurse determine when to take action for what she or he believes is right. Consider the following:

> Alice is a 42-year-old woman with an aggressive cancer that has not responded to previous therapy. She is offered participation in a phase one clinical trial with a promising new investigational agent. Alice's nurse knows that the purpose of the trial is to evaluate the safety of the drug and that the possibility that Alice might benefit in terms of tumor shrinkage or an increase in the length or quality of her life is very small. The nurse is concerned that the principal investigator (PI) has not made this clear enough to Alice, and is concerned that Alice is not well informed about what alternatives are available to her. Respecting Alice's right to make her own decision about study participation, the nurse feels strongly that Alice's informed consent may be compromised. When the nurse raises these concerns, the PI expresses apprehension about confusing Alice. The nurse suggests that a multidisciplinary discussion of the options available for Alice and a plan for assuring she understands the options would be helpful for everyone. The PI agrees. The nurse organizes a patient care conference to include the PI, medical fellow, relevant nursing staff, social worker, spiritual counselor, and bioethicist. All agree that it would be helpful if the nurse spent additional time reviewing information about the study with Alice. After a lengthy and engaging discussion with Alice about the study and her options, the nurse asks Alice to explain in her own words what the study is about, what is likely to happen during the study, and what other choices she has besides participation. Much more confident that Alice has a better understanding of the study and is making an informed choice about participation, the nurse offers continued discussion with Alice throughout the study.

In order to both promote valuable clinical research and protect the rights and interests of people like Alice, it is important to be familiar with ways in which clinical research differs from clinical practice. Without an understanding of the purpose of a phase one trial or the importance of informed consent to research, the nurse might not have taken any steps to help Alice make an informed decision.

Different phases of clinical trials (outlined in Table 2) present different ethical challenges. In the case above, for example, the nurse knew that Alice was being invited into a phase one trial, and believed that understanding the general goals of a phase one study was essential to Alice's informed decision.

Clinical Research and Clinical Care

A source of tension for nurses and other health care providers involved in clinical research stems from differences in goals and methods between clinical research and clinical care.[3] Clinical care encompasses a set of activities designed to promote the welfare and best medical interests of a particular patient. The clinical care provider offers and applies interventions and procedures because they are believed to be safe and effective for the problem at hand. Clinical research, on the other hand, encompasses a set of activities designed to answer a question and generate useful knowledge for the good of future patients or society. Often the rationale for the research is to determine the safety or effectiveness of an intervention for a particular illness. Although individual research participants sometimes do derive medical benefit from research, this is not the primary goal, and some research is not expected to provide any health benefit to participants.[4]

Asking a few individual subjects to assume the burdens of research and exposure to risk for the purpose of benefit to others creates fundamental ethical tension and ethical obligations in clinical research. These ethical obligations include scientific rigor and social accountability, as well as respect for the rights and welfare of individual participants.[5] In many settings, nurses are ethically responsible for contributing to both the promotion of good science and to the protection of the rights and welfare of patient subjects, a balance which requires knowledge, competence, advocacy, creativity, and close working relationships within the research and clinical teams.[6]

Table 3 provides information about codes of research ethics and other documents that have been developed to provide guidance about conducting ethical research and respecting the rights and welfare of research participants.[7] Nurses should be familiar with the major tenets of these codes and know how to access them. Fortunately, educational programs, codes and regulations of research ethics, and other information about clinical research are easily accessible and present opportunities for nurses to learn about the ethical conduct of clinical research. Yet, less than 35% of nurses in one study were familiar with guidelines governing the ethics of research in their department, their facility, or their affiliate university. [8] Importantly, although many useful guidelines exist, ethical research is broader and deeper than any code or set of regulations can specify. Ethical research relies on the knowledge, integrity, and judgment of the people involved. As professionals, it is crucial for nurses to have sufficient knowledge to understand clinical research and its ethical requirements, as well as the courage to act on this knowledge.

Roles and Responsibilities of Nurses in Clinical Research

Nurses can be involved in clinical research in many ways. In recent years the volume of and investment in clinical research – in both the public and private sectors – has expanded dramatically. Research is increasingly conducted in non-traditional sites, including contract research organizations (CROs) and special clinics, private practitioners' offices, and practice research networks.[9] Nurses will encounter clinical research in many settings and will increasingly be called upon to offer information to patients, be involved in recruitment and monitoring, and advocate for the rights of research participants. The Clinical Center Nursing Department at the National Institutes of Health (NIH) recently launched an initiative called Clinical Research Nursing 2010 (CRN^{2010}) with the goal of defining a specialty practice of clinical research nursing and working towards a certification process for nurses practicing in clinical research.[10]

The following sections briefly discuss three unique nursing roles: (a) the clinical nurse as caregiver of patient-participants before, during, or after participation in clinical research; (b) the nurse as study coordinator or clinical trial nurse who works closely with the principal investigator to coordinate all aspects of a study, and who may function as a kind of case manager for research participants in the study; and (c) the nurse as principal investigator on a research study responsible for designing, planning, and conducting clinical research. Each of these roles has its own set of particular ethical challenges.

Clinical Nurse Caregiver and Research

A clinical nurse might be the first point of contact that a research volunteer has with the clinical research enterprise. The nurse's role could include sharing information about studies that patients might be eligible for, general education or information about clinical research, answering questions about specific trials, consultation with clinical research staff, referring patients, and then collaborating with clinical research facilities in the participant's care. A clinical nurse or clinical research nurse might also be employed by a health care facility that conducts clinical research, and therefore may as a staff nurse directly care for individuals who are participating in a clinical trial. Nurses sometimes support study implementation within the

context of clinical care in dedicated clinical research settings, such as the NIH Clinical Center or in clinical research units located in academic medical centers across the country.[11] The nursing care provided to research participants takes into account study requirements and the collection of research data as well as clinical indications and patient care needs. The clinical nurse might, for example, administer investigational medications, perform a detailed clinical assessment, collect research samples, and communicate with the research team regarding observed results. Additional or specialized nursing care may be necessitated by the response of the participant to a study intervention.

The clinical nurse might have more direct contact with individual research participants than other members of the research staff. The relationship of the nurse with the research participant might also extend beyond the clinical trial, in either direction. For example, in a community practice setting, a nurse might care for a patient for several years before the patient is referred for a clinical trial at an urban research center. The community practice nurse will hopefully maintain a supportive relationship with the patient while s/he is participating in the trial and resume the primary care relationship when participation is complete. Good communication between the research center and the referring office helps to minimize possible misinformation or frustration that could affect the patient's experience.

Since a clinical nurse could influence a patient's decision about participating in a clinical trial, the nurse should understand what research is and what the particular trial is about. Take for example, patients participating in a clinical trial for testicular cancer. This trial involved investigational chemotherapy along with computerized tomography monitoring and two laparotomies – one pretreatment and one post treatment – to measure response to the chemotherapy. Not understanding the need for the second laparotomy, the nurse was concerned that it subjected the patient to unnecessary and possibly objectionable risk. Only after asking questions and learning about the purpose and details of the study was the nurse able to appreciate the need for the second laparotomy and fully support the patient in this trial. Several studies have shown a relationship between familiarity with research methods and procedures and nurses' acceptance of and support for research. [12–14]

The clinical nurse providing care to a patient participating in a clinical trial may not have any other involvement in the research other than direct and frequent access to the patient and his/her family or support system. As the caregiver, however, the nurse might be the first to recognize and communicate adverse events, lack of adherence with study requirements, or the impact of participation on the patient-volunteer's disease and psycho-social situation. The nurse may be in the best position to notice an adverse event cluster, especially when it includes common symptoms like fatigue, anorexia, and arthralgias, and can help to distinguish such adverse events from natural disease progression. Clinical nurses caring for research participants need accurate and up-to-date information about the disease under study as well as the particular objectives, interventions, procedures, and ongoing findings of the clinical trials that involve their patients. The research team should make such information available to the clinical nurse, and help the nurse recognize his or her role in communicating critical data to the research team. Collaboration, interest, and participation of clinical nursing staff are essential to the successful and ethical conduct of clinical research.

Clinical Trials Nurse/Study Coordinator

Many nurses function as study coordinators, research coordinators, or clinical trial nurses (CTN). These roles may vary from organization to organization, but there are elements common to many settings. Some nurses who transition from a clinical position to that of a study coordinator or CTN at first experience a sense of isolation and lack of support in these

roles. In addition, they are often surprised by conflicts with or a perceived lack of interest by clinical nurses.[15]

The primary responsibility of the CTN is to safeguard the integrity of the study while managing study participants. Each study has specific requirements that must be adhered to in order for the results to be valid and interpretable. The CTN works to assure that the study requirements are met consistently, while balancing the safety and rights of research participants. Research nurse coordinators or CTNs are usually responsible for study coordination and data management, often including responsibility for managing subject recruitment and enrollment, and screening for eligibility. CTN's provide education and counseling regarding informed consent, and in some cases obtain informed consent. They ensure consistency of study implementation, accurate collection of specimens, monitoring of subjects throughout the study, and study drug accountability. In addition, the CTN assures the collection, management, and integrity of data, as well as compliance with regulatory requirements and reporting, among other things.[16] Research nurse coordinators are often hired by and report to a principal investigator for support of a specific study or group of studies. A CTN or research nurse coordinator is responsible and advocates for the study, while also advocating for the participant as both a subject and a patient.

The role of CTN has been recognized as a distinct subspecialty by some professional organizations, such as the Oncology Nursing Society (ONS). ONS published an extensive Manual for Clinical Trials Nursing[17] and has a special interest group that publishes educational modules about clinical trials and a regular newsletter for CTNs.[18]

Nurse Principal Investigator

Nursing research to develop a scientific basis for practice is critical to evidence based quality care for patients. Nurses as principal investigators (PI) are responsible for designing, implementing, and analyzing research with the goal of expanding the science base for care. Similar to any clinical researcher, the nurse PI has many ethical obligations with respect to clinical research, including asking a clinically or scientifically useful question, and designing the study, methods, and procedures in a rigorous and feasible manner. The PI must also fairly identify appropriate research participants to be invited into the research, minimizing the research risks and maximizing potential benefits, send the proposal through the appropriate levels of independent review, obtain the informed and voluntary consent of participants, and carefully monitor and respect participants' rights and welfare throughout the study.[19]

Nurses who are researchers face all the ethical challenges inherent in conducting research. In addition, nurse researchers can confront situations that involve tension or intrinsic conflicts between their role as clinicians and that as researchers. In the course of research, for example, a nurse researcher may become aware of, or receive a request for, a health care intervention that a patient may need. Patients should not be expected to appreciate the distinction between the nurse as caregiver and the nurse as researcher. When and how a nurse researcher intervenes depends on the study design, the relationship the researcher has with the participant, and importantly, the nature of and immediacy of the patient's need. Researchers have an obligation to intervene when there is an acute, serious, or life threatening situation. For example, a nurse studying the relationship between diet and hypoglycemia in teenagers would intervene if a teen became syncopal due to hypoglycemia.

In other cases, however, intervening may be incompatible with answering an important research question that the nurse researcher is studying. A nurse surveying teens about their sexual behaviors, for example, might appropriately plan to not provide interventions, education, or referrals at least until the survey questions had been completed. In designing any study, the nurse researcher should anticipate the kinds of interventions that might be needed

and carefully plan how to respond to patient needs during and at the end of the study, including knowing what referral and care options are available.

Decisions about how to intervene and respond to a patient may be particularly challenging in qualitative research, in which the relationship between the researcher and the research participant can influence the direction and the integrity of the data.[20–21] For example, one study concluded that nurses need more research education, team and management support when conducting research, as well as opportunities to debrief after encountering mixed role expectations in the field. [22]

Balancing Advocacies

Regardless of the position that a nurse holds in clinical research, a recurrent challenge is balancing the various advocacies that stem from the role or roles that the nurse plays, advocacies that can and sometimes do come into conflict. These are outlined in Table 4, and include advocacy for the individual as patient, advocacy for the individual as research subject, and advocacy for the research itself. [23]

The professional role of the nurse as patient advocate, as well as nurses' intuitions, may result in the instinctive approach to conflicts from that perspective. The American Nurses Association Code for Nurses describes the nurse as an advocate for the patient. [23] Similarly, the American Association of Critical-Care Nurses identifies patient advocacy as an integral component of critical care nursing and states unequivocally that "(a) nurse's primary ethical obligation is to patients" and notes that "…the professional nurse should advocate the highest quality of health care for patients and families… [and] must judge between the requirements of the study and the changing needs of the patient."[24]

Patient advocacy is integral to nursing in any setting. Nurses generally spend more time with patients than other care providers and are therefore in a primary position to assess and evaluate whether research participation is or continues to be consistent with a patient's best interests, values, and preferences. Occasionally, the nurse may advocate for a reconsideration of the patient's participation in a research study based on changes in the patient's condition or the patient's choices, even though such advocacy could conflict with the expectations of the research team.

The nurse working in any capacity with individuals who are participating in research should be as an advocate for the research participant as participant. This requires some knowledge about participants' rights and the protections in place for human subjects in clinical research. The nurse advocates for the research participant, for example, by helping to assure that the participant understands the study and what she is being asked to do, receives the information needed to make informed decisions before the study starts and throughout its duration, and is aware of her right to withdraw without penalty.

The nurse also has a role in advocating for the research itself. Clinical research is important for advancing health care and our understanding of health for the benefit of patients now and in the future. Whether the nurse is primarily a caregiver, a CTN, or an investigator, there is a responsibility to advocate for and support the goals of research and contribute responsibly to the validity and integrity of the study. Each of these advocacies is important and requires the nurse to recognize and balance them, emphasizing the appropriate priority at any given time. Not surprisingly, the primacy of each of these advocacies shifts depending not only on the nurse's role, but also depending on the specifics of the situation at hand and requires informed and careful judgment. Consider the following examples:

BK works at a community clinic as a primary care nurse and has known some of the clinic patients for many years. Dr. Smith, the physician who runs the clinic recently joined as an investigator for a clinical trial of a new drug for mild to moderate depression. A sign was hung in the clinic advertising the study and Dr. Smith has already mentioned it to several patients. BK has reviewed the study and thinks it is worthwhile and well designed. BK also knows that Dr. Smith is excited about being part of the trial, is counting on the financial support from the pharmaceutical company for the study, and sincerely hopes the drug will be successful. One morning, Mr. N asks BK if he should join the study. During the discussion, Mr. N mentions that he likes and trusts Dr. Smith and thinks that joining the study might make Dr. Smith happy. BK is conflicted because Dr. Smith has asked her to help recruit patients and she knows that Mr. N might be eligible for the study, but Mr. N's reasoning makes her uncomfortable. BK's responsibility to advocate for the study seems in tension with her responsibility to advocate for Mr. N.

BK explains her discomfort to Mr. N, and assures Mr. N that she and Dr. Smith are committed to taking care of him in the best way possible regardless of whether or not he participates in the study. She emphasizes that participating in the study is his choice and one that should be carefully considered. They plan a future appointment and in the meantime agree that Mr. N should look over the study information, take time to think about it, and discuss it with his wife. He mentions that his cousin is a doctor and he will probably also ask her for some advice. BK has advocated for Mr. N as both a patient and a potential research subject.

Consider another example:

KB is a CTN for a phase two clinical trial of investigational treatment for a progressive neurological disorder. A patient presents at the research facility for possible enrollment in the trial who does not speak English and has no health insurance. The trial will require five inpatient treatments each cycle with additional monitoring for toxicity. The patient's husband stopped working in order to care for his wife. They have received an eviction notice from their landlord. The CTN evaluates the patient for eligibility and is concerned that she will not be able to comply with the demanding protocol schedule or have adequate resources (phone, transportation, stable home) to participate safely. The research team proposes a meeting with the patient and with her permission also invites her husband and their adult sons. The situation and concerns are explained. The adult children, who had been shielded from information about the severity of their mother's illness by their parents, offer to move both parents into one of their homes and care for them, providing food, phone, and transportation to help their mother complete the treatment protocol.

The CTN is also concerned that the patient, in reality, has few options, and is potentially vulnerable due to lack of insurance and the language barrier. Treatment within the clinical trial is free, and she is clear that this is an important reason for her interest. The CTN arranges for an interpreter to provide assistance in the discussion of the informed consent, a social worker to explore options for health care coverage, and an ethics consultation to impartially assess the patient's decision and reasoning.

In this situation the CTN advocates for the study (by seeking to enroll eligible subjects that can adhere to the study plan), advocates for a possibly vulnerable subject (by providing an interpreter who can translate the consent discussion and explore alternative options and an ethics consult to address the decision) and also advocates for a patient who is facing a difficult situation and needs treatment for her disease (by involving the family in a supportive discussion to problem solve about the immediate and long-term challenges).

Or this example:

RN is the research coordinator at her institution for a large multi-center clinical trial studying treatment of men with prostate cancer. Participants are elderly men, some are quite ill, and they are randomized into one of three different treatment arms. RN is responsible for recruiting participants at her site, and for seeing them at the clinic each week to collect blood samples, vital signs, and symptom data. RN has been the research coordinator for multiple studies and understands the need for monitoring participant safety and for collecting important data along the way. She is concerned in this study however, that coming to the clinic each week presents a significant burden for some of the elderly ill participants. She is also aware that because this is a multi-center study the PI at her site is likely to be reluctant to vary the study in ways that might change the design. She meets with the PI to explore two possible alternatives for reducing participant burden that could be compatible with the study design: a small cadre of nurses could actually visit the participants in their homes to collect blood and vital signs, and/or the frequency of the blood collection could be reconsidered if there were alternative ways to monitor participant safety without requiring a clinic visit. In this situation RN is exercising advocacy for the study participants (by trying to reduce burden), and for the study (by proposing alternative methods of obtaining needed data that won't compromise the design). (adapted from R. Veatch and S. Fry, *Case Studies in Nursing Ethics*. Lippincott, 1987 p. 244, case 91).[25]

One final example:

NR is the PI of a study investigating environmental factors believed to influence the adjustment and well being of mothers and infants within the first 2 weeks postpartum. As part of the study, NR meets the mothers before they are discharged from the hospital and obtains their consent to make once weekly visits to their home. At each home visit, NR administers a questionnaire to the mothers and observes both the interaction between mother and baby and the circumstances in the home. On one scheduled home visit, NR finds Sue's baby unattended and crying uncontrollably. Sue, the mom, is asleep in the next room and apparently has not heard the baby. NR wants to understand and record this finding, but also feels compelled to attend to the baby, and to look into why Sue was not responding to the baby's crying. After picking up the baby, NR attempts unsuccessfully to wake Sue. Seeing an empty pill bottle by Sue's side, NR calls 911 for emergency assistance, and asks the neighbors how to contact Sue's husband. NR went to Sue's home as a researcher, but intervened as a nurse and advocate for both Sue and her baby.

Conclusion

The nurse's obligation to the patient is tantamount to conducting research in a manner that benefits society by generating useful knowledge while respecting and protecting individuals who contribute to the endeavour. Morally responsible nursing consists of recognizing and responding to situations in the most ethical manner that promotes quality patient care. Knowing, understanding, and addressing the ethical challenges that complicate clinical research are essential functions for all nurses in the diverse roles that are critical to the process.

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Table 1

Types of clinical trials

Treatment trials test experimental treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.
Prevention trials look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vitamins, vaccines, minerals, or lifestyle changes.
Diagnostic trials are conducted to find better tests or procedures for diagnosing a particular disease or condition.
Screening trials test the best way to detect certain diseases or health conditions.
Quality of Life trials (or Supportive Care trials) explore ways to improve comfort and the quality of life for individuals with a chronic illness.

Table 2

Clinical Trial Phases

Phase I. Researchers test an experimental drug or treatment in a small group of people (20–80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects. Many phase 1 trials are testing an agent for the first time in humans
Phase II. Researchers test the experimental study drug or treatment in a larger group of people (100–300) to see if it is effective and to further evaluate its safety.
Phase III Researcher test the experimental study drug or treatment in a larger group still (1,000 or more) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely. Phase 3 trials are usually randomized controlled clinical trials.
Phase IV Researchers **c**ollect additional information after an agent is approved and marketed regarding its risks, benefits, and use in various populations over a longer period of time.

Table 3

Ethical Codes of Research Ethics with urls

1.	Nuremberg Code < http://ohsr.od.nih.gov/guidelines/nuremberg.html>
2.	Declaration of Helsinki < http://www.wma.net/e/policy/b3.htm>
3.	The Belmont Report < http://ohsr.od.nih.gov/guidelines/belmont.html>
4.	Code of Federal Regulations Title 45 Part 46,Protection of Human Subjects <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>
5.	Code of Federal Regulations Title 21 Part 50 Protection of Human Subjects http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50

Table 4

ROLE & ADVOCACY	Patient Advocacy	Research Participant Advocacy	Research Advocacy
Clinical Nurse	The Clinical Nurse's primary role is care and advocacy for the patient.	As patient advocate, the Clinical Nurse also has an important role in making sure that the patient knows about appropriate research opportunities and has needed information about the study and his or her rights as a research participant.	The Clinical Nurse may have a critical role in carrying out procedures consistent with the research plan, and/or reporting symptoms and side effects that may be important to the research question.
Clinical Trials Nurse	Having been trained as a patient advocate, the CTN keeps in mind what is best for the patient when considering the patient as a possible research participant.	CTN has a critical role in ensuring that participants are recruited in a responsible manner, well-informed about the study and that their rights and welfare are protected.	CTN is a pivotal member of the research team working closely with or for the Principal Investigator to successfully and ethically conduct the research.
Nurse PI	The nurse as PI should be prepared for the possible conflict between what is best for the patient and what is best for the research.	The nurse as PI is responsible for protecting the rights and welfare of research participants in his/her study and seeking support from others for the same.	The nurse as PI is responsible for rigorous and quality research design and implementation, conducted in an ethical manner.