



Nursing Roles in a Clinical Research Setting:

A Student's Perspective

There is much more to nursing than I ever imagined. I have had the privilege of interning at the National Institutes of Health (NIH) in Bethesda, Maryland for three consecutive summers in the Intramural Research Training Award (IRTA) program. IRTA traineeships provide opportunities for developmental training and practical research experience in a variety of disciplines related to biomedical research.

By Melissa Amaya

The NIH, a part of the U.S. Department of Health and Human Services, is the “primary federal agency for conducting and supporting biomedical research. NIH scientists investigate ways to prevent disease, understand its causes, develop treatments, and even find cures for common and rare diseases. Composed of 27 institutes and centers, the NIH provides leadership and financial support to researchers in every state and throughout the world” (U.S. Department of Human Health and Services, 2008).

The Clinical Center is one center that plays a major role in the mission of the NIH. It is the nation’s largest hospital devoted entirely to clinical research. It is a national resource that makes it possible to quickly transform scientific observations and laboratory discoveries into new approaches for diagnosing, treating, and preventing disease.

A critical part of biomedical research is clinical research. It is clinical research that answers the question, “Does it work in people?” Specific treatments are investigated in a research study or clinical trial to understand the nature of a disease or the effectiveness of a drug or medical mechanism. In addition, it is essential to understand the treatment’s effects on individuals and on their overall health related quality of life. There are many key components and contributors to clinical research. “The sponsor of the clinical trial provides the primary source of funding. Many times the sponsor is a federal agency such as the NIH. A key person in the research study is the principal investigator (PI): the lead scientist for a particular well-defined research project. The PI takes direct responsibility for completion of a project, directing the research and reporting to the funding agency. The PI often works with a group of researchers who are usually members of a research institution who implement the study.” Nurses may serve in scientific roles including that of principal or associate investigators or they may provide direct care for the research participants in the role of clinical research nurses (NYU Medical Center, 2004).

Nurses have a major role in their contact with patients as well as in collecting data and giving the study treatment. It is extremely important that the nurses understand the treatment and its indications. They must also be attentive to what effects they have and how to ensure patient safety. Many times study medications are being given to people for the first time.

The most important person in every clinical trial is the volunteer participant, often called the research subject. Without these volunteers no clinical research can be done (NYU Medical Center, 2004). It is essential to have volunteers to move forward with the improvement of health care and medicine. It is also important to note that not only do these people volunteer, but they remain dedicated until the research study is complete; this can be a lifetime.

The Institutional Review Board (IRB) is another essential group within each research institution. The objective of the IRB is to ensure the protection of human subjects.

The IRB consists of doctors, advanced practice nurses, scientists, and non-medical persons, often from the community, who must review and approve all clinical research. The Office for Human Research Protections (OHRP) has “regulations that have empowered IRBs to approve, require modifications in, or disapprove research” proposals (U.S. Department of Health and Human Services, 2008). There are three main principles to be observed when dealing with ethical concerns with human subjects. The first principle is autonomy, “which refers to the obligation on the part of the investigator to respect each participant as a person capable of making an informed decision regarding participation in the research study. The investigator must ensure that the participant has received a full disclosure of the nature of the study, the risks, benefits and alternatives, with an extended opportunity to ask questions.” The second principle is beneficence, “which refers to the obligation on the part of the investigator to attempt to maximize benefits for the individual participant and/or society, while minimizing risk of harm to the individual. An honest and thorough risk/benefit calculation must be performed.” The last principle is justice, “which demands fair selection of participants, i.e., avoiding participant populations that may be unfairly forced into participating” (University of Washington, 1998).

Nurses are involved in research both clinically and scientifically. Clinically, nurses have contact with the research subjects, observe them, provide care, and collect research data. Clinical research nurses are on the cutting edge of improvements in healthcare. As one clinical research nurse states “Nurses should have and continue to build upon their knowledge and skills which are required to enable them to become competent in identifying, assessing and acting upon all aspects that may affect the integrity and data of research protocols.” A research nurse coordinator added “I think that one [nurse] must possess three

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things: knowledge, experience and a desire to be in research. Working with patients helps you to appreciate and develop an understanding of the research process and healthcare setting. A commitment and desire to work in research is essential to being a successful nurse in healthcare.”

Scientifically, nurses conduct independent research studies. Because of the natural curiosity and concern for the well-being of patients in healthcare, nurses want to become more knowledgeable about what they can do to contribute to improvement. A nurse scientist at the Clinical Center summarized the importance of nursing research by stating, “The outcomes associated with new treatments go beyond tumor response or disease improvement. The quality of life, functionally, psychologically and socially, of an individual and family is also affected, and nurses play a critical role in understanding and improving these outcomes.”

My experience as an IRTA trainee with the Clinical Center Nursing Department influenced my career choice

as a nurse. After originally pursuing a career as a pediatrician, I became convinced that nursing was a much more rewarding profession and changed my career path. The NIH was able to broaden my outlook on how nurses

interact in the healthcare field. My first summer, I gained the clinical perspective: I observed nurses caring for research subjects when they came in for study visits and data collection. The next two summers I experienced the science portion of clinical research, assisting a nurse scientist with studies involving subjects undergoing hematopoietic stem cell transplantation (HSCT). The research process includes: (1) expert search of the literature, (2) study design and development, (3) implementation and data collection, and (4) analysis and dissemination. During my experience,

I focused on the literature on quality of life for HSCT patients, developing materials for study implementation and data entry.

Along with direct experiences in clinical research and nursing research to develop my nursing skills, during my

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internships I had a mentor to help me see the different components of clinical research and the potential roles for nurses. “Nursing practice is an integral part of nursing education in which clinical mentors play an important role. Mentors’ attitudes, experience, and knowledge influence nursing students and help them to complete their nursing practice with success” (Elcigil, 2006). IRTA students at the clinical center credit their success to quality mentorship. “My mentor gave me the opportunity to create a research topic and share my findings,” one student wrote. “She also allowed me to shadow other nurses [clinical research nurses] to get other perspectives from other research nurses. At the NIH I was able to read and understand protocols.” Another student responded, “I was able to attend the IRB meetings to get the ‘behind the scene’ look at research. I also learned how to do literature reviews to support research.” Good mentors provide a variety of learning opportunities to encourage students to explore conceptual frameworks and apply theoretical knowledge to clinical research practice.

I cannot stress enough the role of nursing in improving the health of the nation and the world. Research plays a crucial role in improving unhealthy lives and in preventing unhealthy lifestyle behaviors that contribute to an increased disease burden. We must dedicate our time to discovering and solving the health problems that we are faced with every day. Getting nursing students involved in clinical research fosters their optimism in future advances in clinical practice. We already know we cannot move forward without a foundation supported with evidence. Our mission as nurses is to ensure good health for all patients and do whatever it takes to aid in healing. ☺

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