



# Informed Consent and Patients With Cancer: Role of the Nurse as Advocate

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Informed consent is an ongoing process, and oncology nurses are important advocates to identify information gaps and patient concerns during this process. This article discusses the rights of research participants from a regulatory perspective. Two case scenarios are presented and discussed to describe how nurses can ensure that patients are truly informed and understand the clinical trial process.

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**A** 57-year-old Caucasian male named Mr. L was newly diagnosed with stage IV pancreatic cancer. He arrived with his wife at the infusion center for a blood draw and education about his newly placed Port-a-Cath®. The oncology nurse overheard Mr. L say, “If the doctor wants me to do it, I will just sign it! I have to do it if he wants me to! I do not understand all this medical stuff but this must be what he wants.” During the education session regarding his Port-a-Cath, the treating nurse asked Mr. L about his understanding of the treatment he was to receive. He replied, “Some sorta experiment. I really do not understand but it’s what the doctor wants me to do.” The nurse explained that the clinical trial was just one treatment option and the patient has a choice to participate. The nurse offered to ask the physician and the research nurse to come to the clinic to explain the trial again to Mr. L and his wife. She then notified the research nurse and physician to inform them of Mr. L’s concerns. The nurse also assured Mr. L that this was just an option and that the team would care for him regardless of his participation in the study. The research nurse then made an appointment for Mr. L and his wife with the physician to review the clinical trial.

## Informed Consent Process

Many times, oncology nurses hear patients’ conversation about their lack of understanding and questions they do not feel comfortable discussing with their physicians or healthcare providers. The example presented depicts a patient who agreed to participate in a clinical trial because he believed the physician expected him to enroll. Despite uncertainty of what it all means, the onus and responsibility of ensuring that the patient understands the research trial is an essential part of the informed consent process and patient participation. Patients’ lack of understanding of the clinical trial can lead to patient dissatisfaction, withdrawal, and increased fear about cancer treatment. Informed consent and the process of ensuring it has occurred are ongoing processes and essential to any clinical trial participation (Biedrzycki, 2010).

The informed consent process protects the rights of the human participant in research and is extremely regulated to ensure the protection of participants. The Belmont Report, established in 1979, identifies the three principles of ethical conduct that all clinical trials involving

humans must follow: respect for person, beneficence, and justice (Klimaszewski, 2008). The report states that informed consent must be an ongoing process and is derived to respect the human participant’s right to decide to participate or decline the clinical trial. Informed consent must also include three essential elements: information, comprehension, and voluntariness.

The principal investigator, oncologist, and the entire study team ensure that those elements and principals are followed. The actual informed consent document needs to provide this information in a format the patient can understand (see Table 1). All informed consents are reviewed and approved by an institutional review board (IRB), whose charge is to ensure human participant protection. The IRB is comprised of members from the community and health professionals who ensure that the consent could be understood by someone with at least an eighth-grade reading level, with language in lay-person terms (Klimaszewski, 2008).

Equally important is the comprehension and understanding of the informed consent. It takes time for the patient to read and discuss the form with the physician or nurse. Many oncology trials include consents that are quite lengthy. After reviewing the consent, the patient should be allowed time to comprehend the consent and have an option to review the consent at least overnight, if desired. Some IRBs mandate that requirement. In cases of emergency, the overnight review mandate may be waived, but this must be documented and reported to the IRB if the step is a mandated requirement; however, that circumstance is very unusual in oncology trials. After reading the document, the patient needs to be given an opportunity to ask questions of the healthcare provider. Comprehension