Marilyn J. Hammer, PhD, DC, RN

The current tenets of informed consent have evolved since the 1940s. The guidelines and mechanisms to ensure respect for persons, beneficence, and justice within today’s sophisticated and vastly evolving research studies warrant revisiting. The following is an overview of future discussions that will examine how informed consent really is within various research scenarios.

The history of informed consent dates back as early as the 16th century (Selek, 2010). The current tenets of informed consent pertaining to the ethical conduct of research on human participants predominately stems from the 1947 Nuremberg Code (National Institutes of Health, 2016), which was created following the Nuremberg trials at the end of World War II. The unethical conduct of research on human participants during the Holocaust, coupled with experiments (e.g., the Tuskegee syphilis study), prompted a more formalized structure for ensuring the wellbeing and autonomy of human participants in research studies. The World Medical Association (2013) created the Declaration of Geneva in 1948 (Fischer, 2006), followed by the Declaration of Helsinki in 1964, to apply ethical principles to medical research involving human participants (Fischer, 2006; Rickham, 1964). A decade later, on July 12, 1974, the National Research Act was signed into law (U.S. Department of Health and Human Services [HHS], 1979). Through this act, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was formed and charged with developing guidelines for the conduct of biomedical and behavioral research. The guidelines were established in the Belmont Report (HHS, 1979; U.S. Department of Health, Education, and Welfare, 1979), which continues to be periodically updated. The Belmont Report describes the general principles of respect for persons, beneficence, and justice, and it outlines the process of obtaining informed consent to ensure that these principles are followed (HHS, 1979). In 1998, an informed consent checklist was instituted (HHS, 1998). Although clearly outlined, defined, and described in consent forms, it is beneficial to revisit how informed participants are when they enter research studies, particularly for patients undergoing treatment for cancer. This article will provide an overview of several areas for consideration.

Clinical Trials as Treatment Options

Entering a clinical trial is voluntary. The individual signing the consent must have the capability to sign in addition to having a full understanding of the requirements, risks, and benefits of the trial (Abhyankar, Velikova, Summers, & Bekker, 2016). However, fear could overshadow the decision-making process. For example, when undergoing treatment for cancer, some patients may learn that no single protocol will guarantee cure; therefore, having options for new pharmaceutical therapies in varying phases of testing can be intriguing. In cases in which standard therapy can only offer the hope of a few years of survival, entering a clinical trial for a new therapeutic may give