Because the National Institutes of Health (NIH) has mandated the inclusion of women in clinical trials, numerous studies focusing on the health and welfare of women have been conducted. Although many of these studies are exploratory in nature, others are structured clinical trials intended to evaluate potentially therapeutic interventions in areas such as cancer prevention. With an increased focus on cancer prevention, additional clinical trials will be needed. Recruitment of participants will be a key factor in the development of new knowledge and effectiveness of prevention strategies to improve the health of women at risk for cancer.

Consistent with the requirements of NIH, all potential participants in clinical studies must be assured of their rights to self-determination. From a research and clinical perspective, an extensive explanation of the potential risks and benefits of study participation is required. The goal of providing information is to enable individuals to make informed decisions. The scientific and ethical implications of assuring the patient’s right to self-determination have been addressed from the healthcare provider’s perspective (Plank, 1994). Plank described how women make treatment decisions. There is some acceptance that informed decisions are made with consideration of the expertise that the physician and patient bring to the decision (Forrow, Wartman, & Brock, 1988; Neufeld, Degner, & Dick, 1993; Pierce, 1993).

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