

# The Payment of Research Subjects: Ethical Concerns

Jeanne Marguerite Sears, RN, PHN

**Purpose/Objectives:** To present models for the payment of research subjects, pros and cons of each, and the application of ethical principles in the current environment.

**Data Sources:** Federal regulations and guidelines, current and historical research, and opinions expressed in the nursing, medical, bioethics, pharmacology, and clinical trial literature.

**Data Synthesis:** Relevant regulations are sparse. A variety of payment models exist, but all are somewhat problematic. Balancing the principles of respect for people and justice in our current society will not be entirely possible. Practice decisions must be made for individual situations. Special care must be taken with patients because they are subject to therapeutic misconception.

**Conclusions:** No model fits all situations, but research nurses can use their skills to evaluate particular applications. As a society, nurses must promote participation in research as a socially responsible activity and prevent unethical payment models from predominating.

**Implications for Nursing Practice:** Oncology research nurses may be involved with the consent process, the development of protocols, and staff education. A thorough understanding of an issue that may impair the consent process or impinge upon subjects' rights is critical to effective and ethical practice.

## Key Points . . .

- ▶ Because regulations are sparse, nurses must be familiar with the ethical principles relevant to respecting paid research subjects as people. Voluntary participation and justice are required, as is the fair selection of research subjects.
- ▶ Nurses have a special duty to consider the effects of recruitment practices on patients, and, because of the principle of therapeutic misconception, special care must be taken for informed consent.
- ▶ The current shift away from the protective approach to justice, an emerging emphasis on the benefits that clinical trials offer to subjects, and the promotion of market-based payment models make attention to the ethical issues involved in research subject payment more critical.
- ▶ As oncology nurses become increasingly more involved in clinical research, a thorough understanding of an issue that may impair the consent process or impinge upon subjects' rights becomes increasingly critical to effective and ethical practice.

As oncology nurses become increasingly involved in clinical research, a knowledge base that includes the ethical issues surrounding subject recruitment becomes more critical (Grady, 1991). High-risk trials are increasingly more common, the economic environment is changing rapidly, and special issues need to be considered with regard to the participation of patients (Guy, 1991; Johansen, Mayer, & Hoover, 1991). Oncology nurses participate in the consent process and in setting payment practices, both as nurse investigators and as research nurses (Grady; Melink & Whitacre, 1991). Nurses must consider the effect of recruitment practices on patients, yet this topic is more complex than one initially might imagine. The difficulty of balancing applicable ethical principles in the current socioeconomic environment in a way that both maximizes voluntariness on the part of the subject and allows for adequate recruitment will be examined. The term "subject," as opposed to patient or participant, will be used for clarity about the power relationship inherent in a research study. Other more empowering terms can obscure this basic relationship (Ganter, 1999).

Whether to pay research subjects and how much is a common issue for many studies, because payment may impair consent through undue inducement, which would negate the voluntariness of participation. A number of different payment models are discussed in the literature, and much debate exists

regarding the proper application of ethical principles and the best interpretation of the limited regulations and guidance available. These approaches are not without weaknesses, and, given the wide variety of research types, different methods may be more appropriate in some situations. The purpose here is not to prescribe a particular model but rather to outline the ethical issues and some of the pros and cons for the various approaches. Despite the focus on monetary payment, nonmonetary incentives or benefits (e.g., the reality or perception of free medical care, academic credit) invoke the same ethical issues and also should be considered carefully.

## Regulations and Guidelines

In general, existing regulations are meager and vague regarding payment to research subjects. The Code of Federal Regulations (CFR) requires that "an investigator shall seek such

*Jeanne Marguerite Sears, RN, PHN, is a clinical support nurse at the Community Health Partnership in San Jose, CA, and a research nurse at the Center for the Health Assessment of Mothers and Children of Salinas in California. She also is a member of the Northern California Cancer Center's Human Subjects Review Committee. (Submitted October 2000. Accepted for publication January 18, 2001.)*