

Ethical Challenges Encountered by Clinical Trials Nurses: A Grounded Theory Study

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OBJECTIVES: To investigate the ethical challenges experienced by oncology clinical trials nurses (OCTNs) during the management of CTs and to examine how they resolve those conflicts.

SAMPLE & SETTING: 12 licensed RNs who had been practicing as full- or part-time OCTNs for a minimum of two years at various academic medical centers in the United States.

METHODS & VARIABLES: Classical grounded theory (CGT), an inductive methodology used to explore a social process in which little is known and to develop a theory grounded in the data, was used, in addition to CGT data analysis strategies.

RESULTS: CGT data analysis revealed the OCTNs' main concern (implementing an undefined job) and the way in which the OCTNs resolve this concern through the process of figuring it out. Figuring it out consists of learning as they go, utilizing their assets, standing their ground, and managing hope.

IMPLICATIONS FOR NURSING: Although some nursing research provides examples of ethical challenges OCTNs might encounter in practice, there is little information regarding how nurses manage those encounters. A theoretical understanding of the OCTNs' experiences managing ethical challenges fills a gap in the nursing literature and provides a framework for how OCTNs manage and respond to challenges in professional practice.

KEYWORDS classical grounded theory; clinical trials nurse; ethics; ethical challenge; clinical trial

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The American Nurses Association (ANA) and the International Association of Clinical Research Nurses (IACRN) in 2016 published *Clinical Research Nursing: Scope and Standards of Practice*, which describes the professional role and obligations of the clinical trials nurse (CTN). That same year, the Oncology Nursing Society (ONS, 2016) published 2016 *Oncology Clinical Trials Nurse Competencies*, standardizing the practice for oncology CTNs (OCTNs) by identifying the knowledge and behaviors of those in this role.

Nurses can assume responsibility for a CT and patients taking part in the CT by recruiting patients, overseeing the informed consent process, managing data, and ensuring regulatory compliance (Offenhartz et al., 2008). Various publications (Kunhunny & Salmon, 2017; Ness & Royce, 2017; Purdom et al., 2017) have provided further explanation of the roles and responsibilities of the CTN and the OCTN in practice. Nursing involvement in CTs is essential to ensure that the ethical responsibility to the patient is met. CTNs constantly balance the clinical care of the patient taking part in the CT and the obligations to the research study by protecting patients while ensuring that quality data are collected.

Much of the literature describes the role of the CTN and the domains of the CTN specialty (ANA & IACRN, 2016; Bevans et al., 2011; Castro et al., 2011; Di Giulio et al., 1996; Hill & MacArthur, 2006; Mori et al., 2007; Offenhartz et al., 2008). Other research has identified the ethical challenges that could arise in protocol compliance and documentation, as well as in the management, recruitment, and retention of patients (Barrett, 2002; Cantini & Ells, 2007; Chamorro & Appelbaum, 1988; Cisar & Bell, 1995; Di Giulio et al., 1996; McEvoy et al., 1991; Ocker & Pawlik Plank, 2000).

Cox and Avis (1996) noted that ethical challenges can develop during CTs that threaten CTNs' and