

Parents' Experiences in Pediatric Oncology Phase I Clinical Trials

Principal Investigator: Stacey Crane, MSN

Mentor: Joan Haase, PhD, RN, FAAN

Dates of Support: 09/01/2015-08/31/2018 **Total Award Amount:** \$100,725.00

Funding Agency: National Institutes of Health and Nursing Research of the National Institute (F31NR015393)

Abstract:

Children with cancer are only enrolled in a phase I clinical trial (P1T) when their cancer is incurable; the mean life expectancy of children enrolled in these trials is just five months.⁴⁹ Although 75% of the children will die within a year, parents primarily enroll children based on hope of cure and prolonging life, though this does not reflect the purpose of P1Ts.^{2,23,49} Parents' other reasons for enrollment include ensuring continuity of care, maintaining quality of life, and altruism. P1Ts burden children with additional medical procedures and toxicities, and may increase child and parent suffering, limit palliation opportunities, and disrupt the dying and bereavement processes.^{4,72} Although nurses play a key role in supporting children and parents throughout the P1T, minimal empirical evidence exists to guide nursing caring for this unique population.^{10,51,61} This study is the first step towards understanding the lived experience of pediatric oncology P1Ts. The **purposes** of this study are to: (1) contribute vital information for use by physicians and nurses as part of the P1T consent process; and (2) serve as a foundation for future intervention development to enhance the experience of parents and children participating in P1Ts. The **specific aim** is to develop a rich, in-depth, phenomenological description of parents' experiences of having a child with cancer participate in a P1T.

Phenomenological research is used to describe commonalities of meaning in the lived experiences of people in similar life situations.^{68,73,74} Based on Colaizzi's methods, an empirical phenomenological approach is planned to identify commonalities and construct an essential structure of parents' lived experiences. Through single unstructured interviews (lasting approximately 60 minutes), parents will fully describe their experiences during their child's participation in a P1T. A follow-up call to each participant 7 to 10 days later will assess for indications of resulting undue distress. After data are analyzed and narratives written, a random sample of participants will be contacted to validate the essential structure. To provide context for described experiences, a demographic form will be completed and information regarding the P1T will be abstracted from the signed P1T consent.

The expected outcome is an in-depth description of parents' experiences during their child's participation in a P1T. This description will facilitate evidence-based consent processes, guide intervention research focused on enhancing the child and parent experience during P1Ts, and ultimately decrease the burdens and improve the well-being of children and parents who contribute to the development of novel cancer therapies at this crucial time in their lives.