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Validating the Clinical Research Nursing Domain of Practice

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Descriptive and experimental research with human subjects has significantly advanced understanding of normal physiology and development, the etiology and course of diseases and disorders, treatment of disease and reduction of disability, and human responses to illness and health status changes. Since the 1940s, great strides have been made in clinical research to safeguard human subjects and ensure scientific integrity through discussion regarding ethical principles underlying clinical research, government regulations, and research staff training worldwide (Breslin, 2008). Consensus on standards for conducting research with human subjects is reflected in the International Conference on Harmonization (ICH) Guideline for Good Clinical Practice (ICH Expert Working Group, 1996), which has become the internationally acknowledged basis for the regulation of clinical research in the United States, European Union, and other countries (Fedor, Cola, & Pierre, 2006). International guidance provides the foundation for multisite, international clinical trials designed to evaluate new research compounds and treatment modalities and determine the potential benefits for individuals and human society as a whole.

Clinical trials are research studies conducted with human subjects and are designed to answer specific scientific questions using controlled experimental methods (Cassidy & Macfarlane, 1991). Trials require collaboration among a variety of agencies, such as academic medical centers, single institutions, cooperative groups, the healthcare industry, private and not-for-profit corporations, and government (Offenhartz, McClary, & Hastings, 2008). To ensure the protection of human subjects and scientific integrity amidst the complexities of the clinical research process, the expertise of various disciplines is required.

Purpose/Objectives: To develop and validate a taxonomy for the domain of clinical research nursing.

Design: Survey.

Setting: Clinical research settings in the United States.

Sample: A purposefully selected expert panel of 22 nurses who were actively practicing or supervising in a clinical research environment.

Methods: A study team consisting of nurses with experience in clinical research synthesized peer-reviewed articles, academic curricula, professional guidelines, position descriptions, and expert opinion. Using the Delphi technique, three rounds of surveys were conducted to validate the taxonomy. The three sequential questionnaires were completed over five months.

Main Research Variables: Activities performed by nurses in a clinical research setting.

Findings: A taxonomy for clinical research nursing was validated with five dimensions and 52 activities: Clinical Practice (4 activities), Study Management (23 activities), Care Coordination and Continuity (10 activities), Human Subjects Protection (6 activities), and Contributing to the Science (9 activities).

Conclusions: This study validated activities for direct care providers and nurses with the primary focus of research coordination. The findings identify a variety of activities that are unique to nurses in a clinical research setting.

Implications for Nursing: Nurses play an integral role in the clinical research enterprise. Validating a taxonomy for the specialty of clinical research nursing allows for roles to be compared across settings, competency requirements to be defined, and nursing organizations to be guided in the development of specialty certification.

Nurses have a strong history of being involved in clinical research. However, nursing practice within the specialty of clinical research nursing only recently has begun to be formally defined (Castro et al., 2008). Significant diversity exists in the educational preparation