

## **Creating the Standard for Specialized Nurse Training in the Phase I Clinical Trials Setting**

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### **1. Background**

The complexity of phase I clinical trials requires specialized nurses dedicated to safe and compassionate care while obtaining quality data collection through a comprehensive understanding of clinical practice. A phase I clinical trial treatment visit consists of safety measures and research requirements including adverse event assessments, preventative interventions for toxicities, research lab requirements and frequent vital sign monitoring including electrocardiograms. These observations are paired with detailed documentation necessary in monitoring drug activity and patient safety. It is essential to have a nursing staff trained to navigate complex research protocols in an effective and efficient manner that benefits both patient and research study needs.

### **2. Goals**

In January of 2019, The Phase I Unit at Winship Cancer Institute (WCI) of Emory University relocated to a new, larger, state of the art unit. To ensure excellent patient care and research conduct, the nursing team is required to complete comprehensive certifications and training. The phase I nurses at Winship are required to complete Collaborative Institutional Training Initiative (CITI), Good Clinical Practice Program (GCP), certification in oncology nursing through the Oncology Nursing Society (ONS), completion of the chemotherapy and biotherapy course through ONS, ACLS certification and completion of a Phase I clinical trials specific orientation. This orientation is an in-depth review of clinical trial design, protocol overview, principles of pharmacokinetics and documentation practices that allow grading of adverse events (AEs). The nurses are trained to review all phase one trial order sets for accuracy prior to trial initiation and meet with the research coordinator prior to cycle 1 day 1 to ensure the patient can be treated efficiently and accurately on day 1. The target nurse to patient ratio of 1:2 in the new unit is reflective of the need for specialized care.

### **3. Solutions and Methods**

Deviations from protocol requirements can impact patient outcomes and facility integrity as a compliant research site. At WCI, once a research coordinator has become aware of a deviation, the report is entered into a database. A comprehensive review of deviation data from 2017-2018, revealed lower deviation rates within the Phase I Unit. This is due to the Phase I team's comfort with trial complexity, multidisciplinary care planning, patient acuity and specialized training, along with appropriate nurse to patient ratios.

### **4. Outcomes and Future Directions**

Specialized nurse orientation and continued training within the phase I clinical trial field is imperative in creating a standard of practice and expertise. Development of acuity scales capturing specialized clinical trial conduct will better inform appropriate staffing with ideal staffing ratios that will positively impact treatment practices in the future. Consequently, clinical trials must be viewed as an area of expertise in

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oncology nursing. Future development of a standardized manual for nurse training as well as the development of a clinical trials nurse certification will drastically escalate the overall standard of practice of clinical trials nurses.