# Translational Research Unit

## Development of nursing standards and practice within a specialized unit for participants in early phase clinical trials

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**BACKGROUND:** A growing need exists to ensure safe and skilled oncology nursing care for an increasing number of patients enrolled in phases 1 and 1/2 clinical trials and to provide detailed adherence to protocol administration. This can be best accomplished in a dedicated area for patients in early phase clinical trials.

**OBJECTIVES:** Nursing standards and practice within a newly established translational research unit at an academic medical center were developed.

**METHODS:** A portion of an existing outpatient infusion room composed of 13 beds and a sub-waiting room with 2 chairs was designated for placement of patients enrolled in early phase clinical trials. The functional and safety requirements needed to successfully care for these patients while meeting the demands of the trial protocol drove the creation of this dedicated unit.

**FINDINGS:** Development of dedicated space provided opportunities to define the role of the nurse and hardwire patient and staff safety practices that assisted in reducing study deviations.

**KEYWORDS**
clinical trials; phases 1 and 1/2; safety; translational research unit; nursing skills

**DIGITAL OBJECT IDENTIFIER**
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**MOVING NATIONAL CANCER OUTCOMES FORWARD** depends on the work done during clinical trials. The Cancer Moonshot Task Force report reinforces this by providing a national goal of leveraging efforts to support cancer research, enabling rapid movement forward in the areas of prevention, diagnosis, and treatment (White House, 2016). Prior to this report, a growing academic medical center practice with a desire to increase the amount of clinical trials available for patients identified the need for geographically clustering the care of the increasing number of patients enrolled in early phase clinical trials. Caring for patients in clinical trials usually involves additional personnel and more complicated protocols that deviate from standard practice, all of which lead to safety concerns for patients and staff (Ermete, 2012). Acknowledging this, the Clinical Cancer Center at Froedtert and the Medical College of Wisconsin Froedtert Hospital in Milwaukee created a common area to allow appropriate environmental space and dedicated nursing staff familiar with the intricate details of clinical protocols. This common area is known as the translational research unit (TRU). The key goals of the unit were to ensure patient and staff safety while maximizing protocol adherence.

### Pre-Planning

The role of the oncology nurse in the TRU was guided by the Oncology Nursing Society standards of practice (Brant & Wickham, 2013). To plan and initiate the operation of the TRU, the following questions were addressed:

- What are the skills sets and expectations of the staff nurse?
- What makes the care of a patient in a clinical trial different?
- How should the institution set nursing standards and provide organizational support and a safe environment for practice?
- How would systems be put in place to support the expectations?
- What would the environment need to be like?

To gain knowledge for planning the TRU, contact was made with a nurse consultant (educator) at the National Cancer Institute (NCI), and educational planning resources were obtained. Several NCI-designated comprehensive cancer centers with research units were identified, and contacts were established. Visits were made to three sites to explore unit design and practice issues. The establishment of the TRU would allow for