Category: Clinical Research Operations – Completed Project

Designing a Phase One Clinical Trial Unit: A Multi-Disciplinary Collaborative Approach

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1. Background

In 2009, the Winship Cancer Institute of Emory University opened its initial Phase I Clinical Trials Unit to integrate patient care and research for patients enrolled on translational early phase studies. As the Phase I program continued to grow and diversify, a need for a larger unit with greater capacity for groundbreaking trials emerged. In 2018, the team embarked on the creation of a new unit utilizing an integrated facility design (IFD) process. The IFD approach was selected as it is a multi-disciplinary, comprehensive process focused on creation of an ideal environment for patients, caregivers, researchers, providers and nurses. Patient and staff agreed comfort, safety and functionality needs should drive the design of the space using prior philosophies and the IFD method.

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2. Goals

Project governance outlining the vision and goals for the creation of a new cutting edge phase I unit was established. A primary objective was to encourage people using the unit, especially staff and patients, to design a space that allows for translational research and excellent patient care with a focus on quality improvement initiatives for the future.

3. Solutions and Methods

Multidisciplinary teams including providers, nurses, research coordinators, pharmacists, patient family advisors, laboratory, and operations team members were assembled. Process mapping, time studies, voice of patient/staff/leadership interviews were conducted; and unit volume data were benchmarked to better establish current volumes and processes for future projections and improvement opportunities. Upon completion of the pre-work, multi-day workshops across 2 different weeks were conducted to brainstorm the ideal patient and staff experience in a phase I research program. The establishment of visionary patient care and research conduct processes as well as agreed-upon critical adjacencies laid the foundation for the physical unit design. Upon completion of several draft layouts, each version was vetted for team established adjacencies and flow needs.

A life size cardboard version of the proposed final unit rendering was built overnight. Multidisciplinary teams toured the mockup to provide critical feedback allowing for real-time changes to the cardboard layout. The team finalized the unit design, submitted it for leadership input and approval followed by the start of construction. The new unit features 15 private treatment rooms, 4 consult rooms and a 3 chair fast track area. Key tenets of the final design included patient and family comfort, patient line of sight for the nursing staff, a research lab that tripled in size and integrated multidisciplinary work stations throughout the unit allowing optimal communication and research conduct.

4. Outcomes and Future Directions

Design of a phase I unit focused on the ideal flow, functionality, safety and patient experience determined by patients and staff using the space, resulted in an environment that supports full integration of excellent patient care and precise research conduct.