

## **Simulation-Based Training to Enhance Clinical Research Skilling: a Practice Based Exploratory Pilot Study**

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### **1. Background**

Oncology clinical trials continue to face persistent challenges in participant recruitment, retention, and informed consent. These challenges are intensified by increasingly complex study designs, emotionally charged clinical contexts, historical mistrust in research, and variability in research staff communication skills. Although communication is central to ethical recruitment and high-quality trial conduct, most clinical research workforce training remains primarily didactic, with limited impact on real-world performance. Simulation-based mastery learning (SBML) has demonstrated effectiveness in improving communication behaviors in clinical care settings through deliberate practice, structured feedback, and competency-based assessment. However, SBML-informed approaches remain underutilized within the clinical research workforce, particularly in oncology. There is a critical need for experiential, practice-based training models that can be embedded within real-world research operations and aligned with principles of implementation science to support sustainability.

### **2. Goals**

This project proposes a simulation-based communication training model designed for oncology clinical research staff involved in recruitment, consent, and trial conduct within the Clinical Trials Office at Penn State Cancer Institute. As an idea-stage initiative, the primary goal is to establish a feasible and scalable educational model that integrates SBML principles into institutional workforce development. Secondary goals include tailoring training to role-specific competencies across the clinical trials office, fostering learner confidence and preparedness, and generating early implementation knowledge to inform future effectiveness and sustainability studies. Distinct learner groups—including clinical research nurses, clinical research associates, data managers, and regulatory staff—will participate in shared simulations while being evaluated using role-specific performance metrics aligned with their responsibilities. The first pilot cohort is scheduled to launch March 2026. No outcome data are available at this stage.

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

The intervention uses structured, scenario-based simulation modeled after Group Objective Structured Clinical Experiences (GOSCEs). Training sessions incorporate standardized participants, facilitated group debriefing, peer observation, and criterion-referenced assessment consistent with SBML methodology. Three oncology-specific scenarios were developed to reflect common and challenging communication contexts: (1) engaging a prospective participant with sensory or communication barriers; (2) navigating family disagreement regarding trial participation; and (3) addressing mistrust in research informed by historical or personal experiences. Deliberate practice cycles and structured feedback are designed to support behavioral skill acquisition and mastery. From an implementation science perspective, the program emphasizes feasibility, acceptability, appropriateness, and adaptability within existing

institutional education structures. A pre/post evaluation framework has been developed to support future assessment of confidence, perceived preparedness, and implementation outcomes, although no empirical results are reported at this time.

#### **4. Outcomes**

As an idea-stage project, no empirical outcomes are available. Anticipated individual-level outcomes include increased confidence in research communication skills and improved readiness to manage emotionally complex recruitment and consent conversations.

#### **5. Lessons Learned and Future Directions**

Organizationally, the program is expected to demonstrate the feasibility of integrating SBML-informed simulation into routine oncology research education and to provide foundational data to inform future studies examining effectiveness, fidelity, and scalability. Future directions include iterative refinement of scenarios, expansion to additional oncology research roles, and formal evaluation of downstream impacts on recruitment quality, consent processes, and trial conduct.