Simulation-Based Training to Enhance Clinical Research Skilling: A Practice-Based Exploratory Pilot Study

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Training, Career Development & Staff Retention | Work in Progress

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.

SBML-informed approaches remain underutilized within the clinical research workforce, particularly in oncology. There is a critical need for experiential, practice-based training models embedded within real-world research operations and aligned with principles of implementation science to support sustainability.

2. Goals

Establish a feasible and scalable educational model that integrates SBML principles into institutional workforce development within the Clinical Trials Office at Penn State Cancer Institute.

- Tailor training to role-specific competencies across clinical research nurses, clinical research associates, data managers, and regulatory staff.
- Foster learner confidence and preparedness for emotionally complex recruitment and consent conversations.
- Generate early implementation knowledge to inform future effectiveness and sustainability studies.

The first pilot cohort launched March 2026. No outcome data are available at this stage.

Session at a Glance — March 2026

Protocol: A representative oncology clinical trial reflecting typical CTO research activity — complex study design, multi-arm, and emotionally salient for participants
Trainees: Clinical Research Nurse (CRN) · Clinical Research Associate (CRA)
Observers: Simulation Center leadership, CTO Research Educator, Clinical Trials Community Specialist, onboarding staff
Scenarios: Conflicting Perspectives · Highly Anxious Patient
Debrief: Three-phase facilitated debrief: Reaction → Analysis → Summary

3. Solutions & Methods

The intervention uses structured, scenario-based simulation modeled after Group Objective Structured Clinical Experiences (GOSCEs), incorporating standardized participants, facilitated group debriefing, peer observation, and criterion-referenced assessment consistent with SBML methodology.

- Pre-Brief: Psychological safety contract, mastery standard, scenario background
- Simulation: Learner conducts consent discussion with Standardized Participants (SPs)
- SP Feedback: Structured behavioral reflection: "When you said/did [X], I felt [Y]"
- Facilitator Debrief (10–15 min): Reaction → Analysis → Summary

Three oncology-specific scenarios: (1) Conflicting Perspectives regarding trial participation (2) Highly Anxious Patient

From an implementation science perspective, the program emphasizes feasibility, acceptability, appropriateness, and adaptability within existing institutional education structures.

4. Outcomes

As an idea-stage project, no empirical outcomes are available.

- Anticipated: Increased confidence in research communication skills and improved readiness to manage emotionally complex recruitment and consent conversations.

Organizationally, the program is expected to demonstrate the feasibility of integrating SBML-informed simulation into routine oncology research education and to provide foundational data for future studies examining effectiveness, fidelity, and scalability.

5. Lessons Learned & Future Directions

The March 2026 pilot demonstrated that SBML-informed simulation is feasible and acceptable within a functioning Clinical Trials Office.

- Simulation Education Observation Room enabled rich peer observation: staff scored rubrics in real time while viewing the live simulation feed.
- Role-specific scoring criteria supported differentiated, meaningful feedback for each learner group.

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.

Fig. 1 — CTO staff observing the live simulation

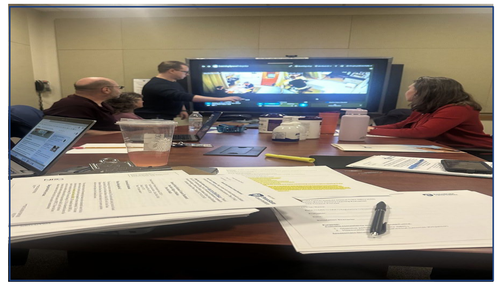

Fig. 2 — Simulation setup

SBML Scoring Rubric — Informed Consent Process Evaluation (Penn State Cancer Institute | Clinical Trials Office)

SCORING SCALE: 1 NOVICE Incomplete, inaccurate, or missing behaviors | 2 COMPETENT Correct but inconsistent or mechanical | 3 MASTERY Consistent, accurate, fluent, patient-centered

Competency	1 — Novice	2 — Competent	3 — Mastery
Domain 1: Regulatory & Content Accuracy			
Study Purpose	Unclear or incorrect	Accurate but basic	Clear, concise, patient-centered
Procedures	Missing key elements	Mostly complete	Complete and well-organized
Risks	Incomplete or minimized	Accurate, not contextualized	Clear, balanced, understandable
Benefits	Overstated or unclear	Accurate	Realistic, non-coercive framing
Alternatives	Not discussed	Mentioned	Clearly explained
Voluntariness	Not emphasized	Stated once	Reinforced clearly and ethically
Confidentiality	Missing or vague	Basic explanation	Clear and reassuring
Domain 2: Communication & Patient Engagement			
Plain Language	Heavy jargon	Mostly clear	Fully accessible language
Active Listening	Minimal	Demonstrated	Highly responsive, adaptive
Non-verbal Skills	Poor engagement	Adequate	Strong rapport-building
Empathy	Absent	Occasional	Consistent and authentic
Open-ended Questions	Not used	Used occasionally	Used strategically
Patient Concerns	Ignored	Addressed	Explored deeply, respectfully
Domain 3: Understanding & Teach-Back			
Teach-Back Use	Not used	Attempted	Effective and natural
Clarification	Misses misunderstandings	Addresses some	Fully resolves confusion
Summary	Missing	Basic	Clear, structured recap
Domain 4: Ethical Conduct & Autonomy			
Coercion Avoidance	Potentially coercive	Neutral	Clearly autonomy-supportive
Decision Support	Not provided	Minimal	Encourages reflection/time
Respect for Patient	Inconsistent	Adequate	Fully patient-centered
Domain 5: Process & Documentation			
Consent Workflow	Disorganized	Functional	Smooth and structured
IRB Form Use	Incorrect	Correct	Fully compliant, explained
Next Steps	Missing	Mentioned	Clear and reassuring

Fig. 3 — SBML Evaluation Rubric: 5 Domains, Scale 1 (Novice) → 2 (Competent) → 3 (Mastery) | Penn State Cancer Institute CTO