SCRIIPTT Project Overview

The overarching goal of the *Simulation-based Community-engaged Research Intervention for Informed Consent Protocol Testing and Training (SCRIIPTT)* project is to incorporate culturally and linguistically competent methods into the informed consent process using the expertise of community members. It will be implemented through a community-academic partnership between Mosaic Cultural Complex, the UMass Center for Health Equity Intervention Research (CHEIR), the CCTS Bioethics Core, and the UMMS Office of Educational Affairs' Inter-professional Center for Experiential Learning and Simulation (iCELS). The core of the project is the Community Advisors who are individuals from the Worcester community. Community Advisors are a part of the Research Team. There are four key activities:

Community Forum. We will begin with hosting a community forum using the Truth & Reconciliation Model developed by the National Center for Cultural Competence (NCCC) and the Georgetown-Howard Universities Center Clinical and Translational Science. The goal is to begin breaking barriers and initiating an affirmative relationship among community members, academic research staff and the project.

Focus Groups. We will implement two focus groups to better understand the community's perceptions about research and trust, and knowledge of the informed consent process.

Development Workgroup: In addition to the expertise of the Community Advisors, we will pull from the information gathered in the community forum and focus groups to develop the intervention protocol.

Simulation-based Intervention: The intervention is a simulated interaction in which the informed consent process is administered by a research assistant to a community member who is trained to act as a potential research participant. It contains four components: (1) *Pre-brief*: The intervention will begin with Community Advisors providing the research assistants with the study materials (e.g. project overview, inform consent form) and, training the research assistants in the components of culturally appropriate informed consent. (2) *Simulation*: In the iCELS lab, research assistants will deliver the informed consent to the community member who is trained to act as a potential research participant. The setting will be configured to mirror the real-world in which informed consent occurs, including the busy clinic, community, or hospital setting. (3) *Debrief*: After the research assistant completes the informed consent encounter there will be a structured debriefing session with Community Advisors. (4) *Deliberate Practice*: Following the debrief, research assistants will have the opportunity to repeat the simulated encounter and deliberately practice and perfect those skills that require further development in order to achieve the expected level of competency in the informed consent protocol, as discussed with the Community Advisor.

Contributions from communities of color are valuable in addressing barriers due to medical mistrust. SCRIIPTT imprints the voice of the community on the informed consent process, which remains a potentially vexing obstacle to engagement. We will integrate two innovative strategies that engage community members: (1) building communication and engagement through the Truth and Reconciliation Model, a process that begins with acknowledgement of past wrongs committed in the name of biomedical research and moves on the focus on productive collaboration and mutual benefit and (2) intervening to improve the culturally appropriate delivery of informed consent using state-of-the-art simulation techniques to promote experiential learning in a safe environment that replicates the demands and stresses of the "real-world".

The Research Team:
Mrs. Brenda Jenkins, Community PI
Dr. Jeroan Allison, Academic PI
Ms. Marie Boone, MHS
Dr. Michele Pugnaire
Dr. Brian O'Sullivan
Mrs. Tawara Goode, MA
Ms. Lauren Powell
Mr. John Trobaugh, MFA
Ms. Chioma Nnaji, MPH, MEd