

Starting off on the Right Foot: Elevating the Voice of Community Stakeholders During the IIT Development Process

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1. Background

The IIT Think Tank (I2T3) was established in January 2020 to increase the quality and quantity of UFHCC investigator-initiated trials (IITs) while simultaneously supporting career development for early-stage clinical investigators. In late 2021, the I2T3 was further enhanced through a new partnership using a cohort of community members to increase the patient-centeredness of our concepts to individuals with cancer within our catchment area. To that end, we partnered with UFHCC Office of Community Outreach and Engagement (COE) and their citizen scientist (CS) program to include community member feedback on IIT protocol concepts, as well as recruitment and retention strategies.

2. Goals

Our two primary goals are to:

- a) Establish a sustainable collaborative culture between the community and early-stage investigators via an ongoing partnership between I2T3, COE, and CS to meet our community needs
- b) Improve the patient-centeredness of IITs through community feedback on interest, recruitment, and impact, from the first discussion of concepts

3. Solutions and Methods

In partnership with UFHCC COE and their CS program, the clinical research office (CRO) invited two community members (citizen scientists, or CS) to I2T3 meetings starting in December 2021 as formal concept reviewers. The CS program was developed as a research partnership model in recognition of the invaluable contributions that citizen scientists make as members of the research team. The CRO's mission in collaborating with this program is to develop research partners who work closely with cancer scientists to address health disparities as partners in the research process. CS receive formal training in health research through general and cancer-specific curricula, including bidirectional communication skills leading to certification as a qualified CS. Each CS is fully integrated into the I2T3 meeting providing verbal and written feedback on all IIT concepts presented. Adequate addressing of any CS concerns by the study team is required, barring documented justification why it cannot, for an IIT to move forward with development. Ongoing partnerships between CS and investigators are encouraged as concepts develop into protocols, including use of CS as a resource and community connection throughout the life of the trial, through support from the UFHCC COE. Beyond assisting with concept and protocol development, CS also assist with reviewing consent forms, patient materials, and grant applications.

4. Outcomes

Implementation of the CS program has yielded positive impact upon cancer research across UFHCC, including feedback on a Patient-Centered Outcomes Research Institute (PCORI) submission for a tobacco cessation study, consulting on responses to FDA queries for a glioblastoma trial, and helping improve feasibility of a head and neck cancer study. To date, CS feedback has centered on innovative strategies to maximize treatment compliance, increase recruitment diversity, and educate subjects about contraindications to treatments and toxicities, across five concepts reviewed.

5. Lessons Learned and Future Directions

We will perform an annual review of feedback provided and track what percentage of CS feedback was ultimately included in protocols, as well as enrollment metrics to assess effects of community feedback on recruitment. We will also collect feedback from investigators and CS to continually improve the program so it can be maximally beneficial to both groups.