

BACKGROUND

As part of ongoing efforts to ensure representation in treatment trials, an analysis of demographic enrollment trends in 2023 identified low enrollment of women relative to our catchment area. To address this disparity, the UFHCC devised a novel Request for Applications (RFA) pilot process to increase opportunities for women to participate in cancer treatment trials. Concepts were solicited to specifically target women. The established UFHCC II Think Tank (I2T3; previously presented at AACI CRI) was used as a peer-review mechanism. Selected concepts were then reviewed and refined via feedback from the multidisciplinary I2T3 team, harnessing a well-developed asset to target the needs of our

GOALS

To assess feasibility of using our established concept development review and refinement process (I2T3) to address areas of need, by soliciting IITs targeted to the specific needs of our clinic population and catchment area.

METHODS

The RFA for treatment concepts to enhance recruitment of women was released in September 2023. Concepts submitted in response to the RFA were reviewed at a dedicated I2T3 meeting reserved for investigator presentation and discussion of submissions. Submissions utilized the UFHCC CRO Concept Review Form, to align the application process with the currently known process for submitting IIT concepts. The ADCR marketed the RFA via email blasts, I2T3, and in DSG meetings, and personally brainstormed with potential applicants in women-focused DSGs (gyn, breast).

A summary table of submissions was created by the Assistant Director for Project Management for initial review to confirm that each met minimum standards for treatment trial classification and administrative feasibility. In total, eight submissions were received and five were selected to proceed with the next stage of review (presentation at I2T3). One of those five had already been presented at I2T3 and had since secured other funding, so that left four submissions for presentation and review at I2T3.

Initial Review Table

Short Title (PI)	Patient Population	Indication Treated	Sample Size	Protocol Type	DT4 Type	Objectives	Study Phase	Intervention

Because attendance at I2T3 has been curated to include diverse expertise, this forum allowed for rich verbal feedback from multiple perspectives (statistics, scientific, feasibility, study design). A Qualtrics survey link was distributed to I2T3 attendees for each concept to collect anonymous written feedback. Post-meeting, a preliminary cost estimate was developed by the Project Management Office (PMO) for each concept. All data was collated for a final selection committee of senior CRO and UFHCC leaders to review. Positive and negative feedback for each concept was discussed, as well as cost, feasibility, and potential for innovation, scalability and impact. The four concepts were assigned a rank order and each of the above dimensions were summarized in a final document for UFHCC Director Review.

OUTCOMES

- Two concepts selected for intramural funding
- PIs of concepts
 - One is an early stage investigator
 - First IIT for both PIs
- Development of concepts completed by PMO
- Goal to open both protocols to enrollment within 6 months of award

FUTURE DIRECTIONS

A similar process is being used in response to other needs assessments performed by cancer center leadership, harnessing expertise represented in I2T3 meetings to drive creation of IITs curated to support the needs of the community.

CONTACT

ERIN MONARI, PhD, CCRC
Director of Clinical Research

University of Florida Health Cancer Center
2033 Mowry Road
Gainesville FL 32610

352-273-8128
clh1230@ufl.edu

