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Empowering Research Leadership: Development of an Intensive Course to Support Oncology Advanced Practitioner Participation in Clinical Trials

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Authors' disclosures of conflicts of interest are found at the end of this article.

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Abstract

Oncology advanced practitioners (OAPs) play an important role in cancer care delivery. However, leadership in clinical research remains low among OAPs. Although OAPs often participate in patient care for early-phase clinical trials, they rarely have the opportunity to lead as a principal investigator (PI), despite being capable and effective PIs when provided education and mentoring. As cancer care needs continue to increase, there is a critical need for well-trained PIs and sub-investigators (sub-Is) to evaluate novel therapeutics. To address this need, an intensive 3.5-day educational course at HonorHealth Research Institute (HRI) was developed to provide education and guidance to OAPs who desire to learn and evolve into the role of a PI in clinical trials. The course involved lectures, roundtable discussions with physicians, and protocol synopsis workshops. Participants included 21 OAPs. Participants were given questionnaires to evaluate the impact of the course and assess knowledge retention. In lectures, 65% of questions answered demonstrated improvement. In course evaluations, 100% of participants agreed that the learning objectives were met. In follow-up surveys, 63% reported they had reviewed their drafted protocol synopsis with their mentor, while the majority felt at least somewhat confident that they would be able to move forward with their protocol synopsis. Overall, participants responded favorably to the course, which successfully provided foundational knowledge for OAPs to transition into clinical research leadership positions.

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Oncology advanced practitioners (OAPs) play key roles in the coordination of care with members of the health-care team and are leaders in providing quality care and symptom management. The prevalence of cancer cases continues to increase yearly (Centers for Disease Control and Prevention and National Cancer Institute, 2024). The number of OAPs also continues to grow to meet the demands of the population. Between 2019 and 2023, the number of nurse practitioners (NPs) grew by 35.5% (National Center for Health Workforce Analysis, 2024). There are an estimated 11,000 OAPs nationwide (Vogel, 2016).

Despite these growing numbers, OAP involvement in clinical research has lagged. A nationwide survey addressing the attitudes, beliefs, and roles of 408 OAPs regarding clinical research demonstrated that 91% of participants reported that OAPs should participate in clinical research; however, only 10% have been a principal investigator (PI) in a clinical trial. The number of OAPs who have been sub-investigators (sub-Is) in a clinical trial increased to 49% (Braun-Inglis et al., 2022). While OAPs often participate in the care of patients in early drug development clinical trials, they rarely have the opportunity to lead an early-phase clinical trial. Physicians typically function in this role as PIs.

Oncology advanced practitioners can be capable and effective PIs with education and mentoring (Jameson et al., 2020). However, there has been no established training or fellowship program specifically designed to prepare OAPs for the role of PI. Given the increasing number of cancer cases, the ongoing acceleration of bench-to-bedside drug discoveries, and the anticipated decline in the number of oncologists, there is a growing need for well-prepared PIs and sub-Is in cancer clinical trials (Cavallo, 2024). Oncology advanced practitioners, as clinical experts, are well suited and permitted by the U.S. Food and Drug Administration (FDA) to serve as PIs in drug studies.

According to the Code of Federal Regulations in CFR 312.53 and 812.43, sponsors of clinical investigators are required to select investigators who are qualified by education and experience as appropriate experts to investigate the test article, whether it is an investigational product or device (Code of Federal Regulations, 2025). Not only does the inclusion of OAPs increase the pool of investigators to execute trials but it can also help patients by advancing the science and the application of novel therapeutics. Due to OAPs' holistic training, OAPs as PIs can raise the bar on the quality of the execution of clinical trials (Downhour, 2018).

In February 2024, HonorHealth Research Institute (HRI) planned and hosted a 3.5-day educational course for OAPs working in clinical trial environments and interested in learning about the role of the PI. In 2018 and 2020, HRI partnered with City of Hope and a similar but smaller scale course was presented. The participants deemed this course extremely effective by increasing their role in clinical research. Based on this experience, we were interested in developing an expanded course at HRI and worked with Dr. Daniel D. Von Hoff (Translational Genomics Research Institute and City of Hope) as the course consultant. The program was modeled after the ASCO/AACR Methods in Clinical Cancer Care Research Workshop, which educates physicians in the role of PI and protocol development.

HonorHealth Research Institute obtained an educational grant from the Cottrell Foundation of Research Corporation Technologies to conduct this course and offer participants a scholarship to attend. Applicants were required to submit curriculum vitae, a letter of intent, and a letter of support from a sponsoring physician, and were interviewed by phone. Twenty-one OAPs were selected to participate in the course and secured for full scholarships, representing 16 major cancer centers. With 25 participating faculty, the course included 25 didactic sessions, and 22 continuing medical education units were offered for course completion.

COURSE SUMMARY AND OBJECTIVES

This course was developed by HRI and designed to enable OAPs to become PIs in clinical trials. Participants included 19 participants from the United States and 2 from Australia. Of the 21 participants, 16 were NPs, 4 were physician associates (PAs), and 1 was a clinical nurse specialist (CNS). All participated in the 3.5-day course agenda consisting of lectures, roundtable discussions, and hands-on protocol development to meet the following objectives: (1) Describe the roles and responsibilities

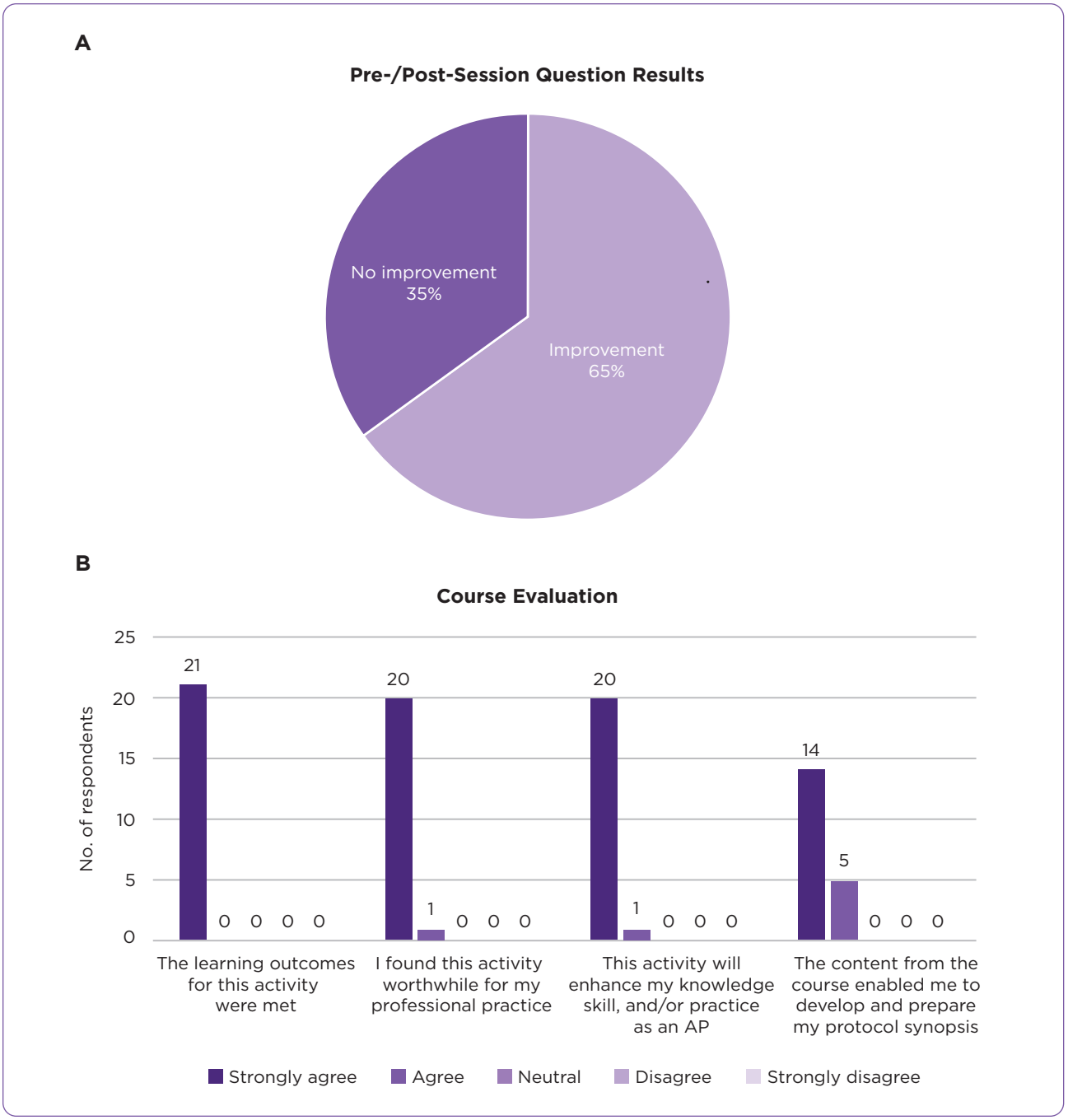


Figure 1. Course results. (A) Percentage of questions that demonstrated improvement/no improvement in correct answers pre- and post-session (n = 20). (B) Course evaluation results gauging participants' agreement with statements (n = 21). Two participants selected "Other" on question 3, which is not reflected on the graph. AP = advanced practitioner.

as both PIs and sub-Is in early cancer drug development and cancer clinical trials; (2) describe the pre-clinical (laboratory) work required before proceeding to phase I clinical trials in human studies; and (3) develop a protocol synopsis.

Lecture materials focused on clinical trial design, data collection, and data management. Roundtable discussions were conducted with physician oversight, and feedback on protocol ideas was provided over the 3 days. On the final

Table 1. Improvements to Practice as a Result of Attending the Course Reported in Post-Course Evaluation

Impact to Practice	*n*	%
Define the basic principles of the advanced practitioner in oncology clinical trials	20	95
Improve my communication with the care team	18	86
Evaluate the indications for enrolling patients in oncology clinical trials	18	86
Identify the indications, risks, treatment options, and complications of enrolling patients in oncology clinical trials	17	82
Demonstrate appropriate pharmacologic management in the care of patients with cancer	15	71
Improve system processes	14	67
Analyze the latest trials for oncology patients	14	67
Recognize the current treatment options and management of oncology patients	13	62
Formulate a treatment algorithm for enrolling patients in oncology clinical trials	13	62
Improve my patient education skills	13	62
Interpret biomarkers, genome, and genetic determinants of patients with cancer	12	57
Deliver more culturally responsive care	5	24

half day, each participant presented the initial concept of the protocol synopsis for discussion, and recommendations from the team were provided. Participants were encouraged to continue to develop their protocol synopsis beyond the course for potential clinical implementation.

PRE- AND POST-TEST ASSESSMENT AND COURSE EVALUATION

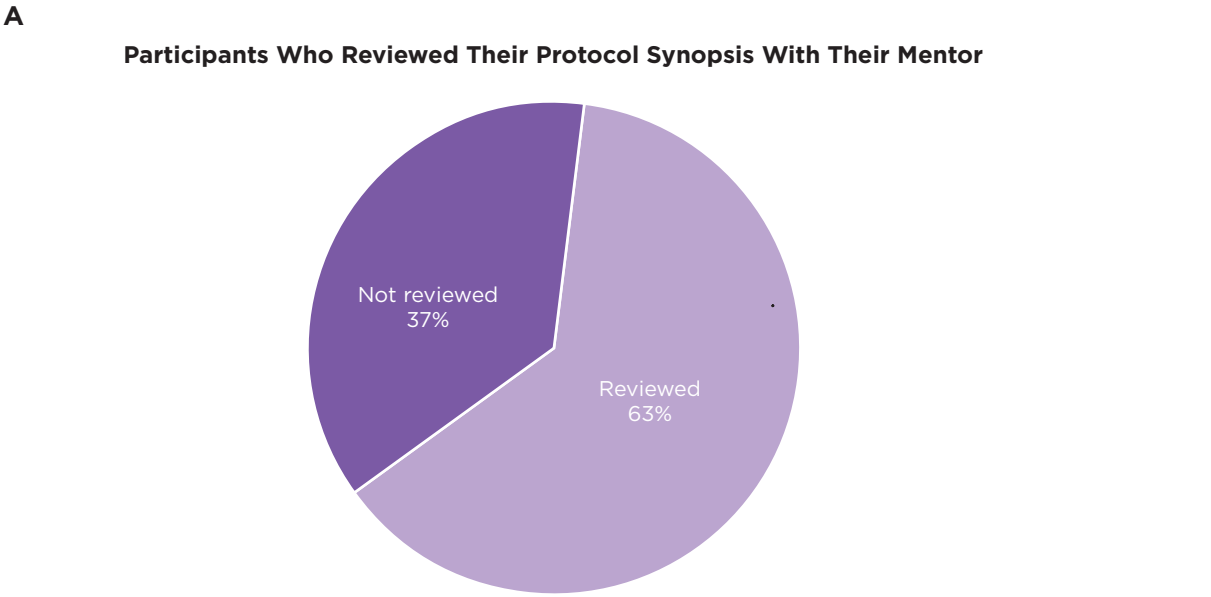
Questions to assess knowledge were administered daily via a QR code at the beginning (pre-test) and end (post-test) of each session, totaling six questioning rounds with a total of 20 questions. Participation was high among participants, with a 100% response rate noted per day. When comparing pre-test and post-test answers, 65% (13/20) of questions demonstrated improvement in either one or more correct answers or consistency in correct answers over the duration of the course, while 35% (7/20) of questions did not demonstrate improvement (Figure 1A). This may be due to participants' prior knowledge, multiple question designs, and potential survey fatigue.

At the end of the course, all participants were asked to complete an evaluation with various multiple-choice questions and open-ended responses. When asked how strongly they agreed that the learning outcomes for this course were met, 100% (21/21) strongly agreed (Figure 1B). Additionally, 100% (21/21) strongly agreed that as a result of this activity they would be able to describe the role of the OAP as both PIs and sub-Is in early drug development research. When participants were asked if the course was worthwhile for professional practice and if the course enhanced their knowledge, skill, and/or practice as an OAP, 100% (21/21) agreed or strongly agreed (Figure 1B). When asked if they believe the contents of the course enabled them to develop and prepare their protocol synopsis, 91% (19/21) of participants agreed or strongly agreed (Figure 1B); two participants responded as "Other" for this question and shared positive anecdotes regarding the roundtable discussions and specific participating physicians.

In a multiple-choice question regarding various improvements to practice, the top four improvements identified were: (1) Define the basic principles of the advanced practitioner in oncology clinical trials (95%, 20/21); (2) improve my communication with the care team (86%, 18/21); (3) evaluate the indications for enrolling patients in oncology clinical trials (86%, 18/21); and (4) identify the indications, risks, treatment options, and complications of enrolling patients in oncology trials (82%, 17/21) (Table 1).

Follow-Up Assessment

A four-question follow-up survey was sent to participants at 1 month and an eight-question survey at 6 months post-course. On the 1-month follow-



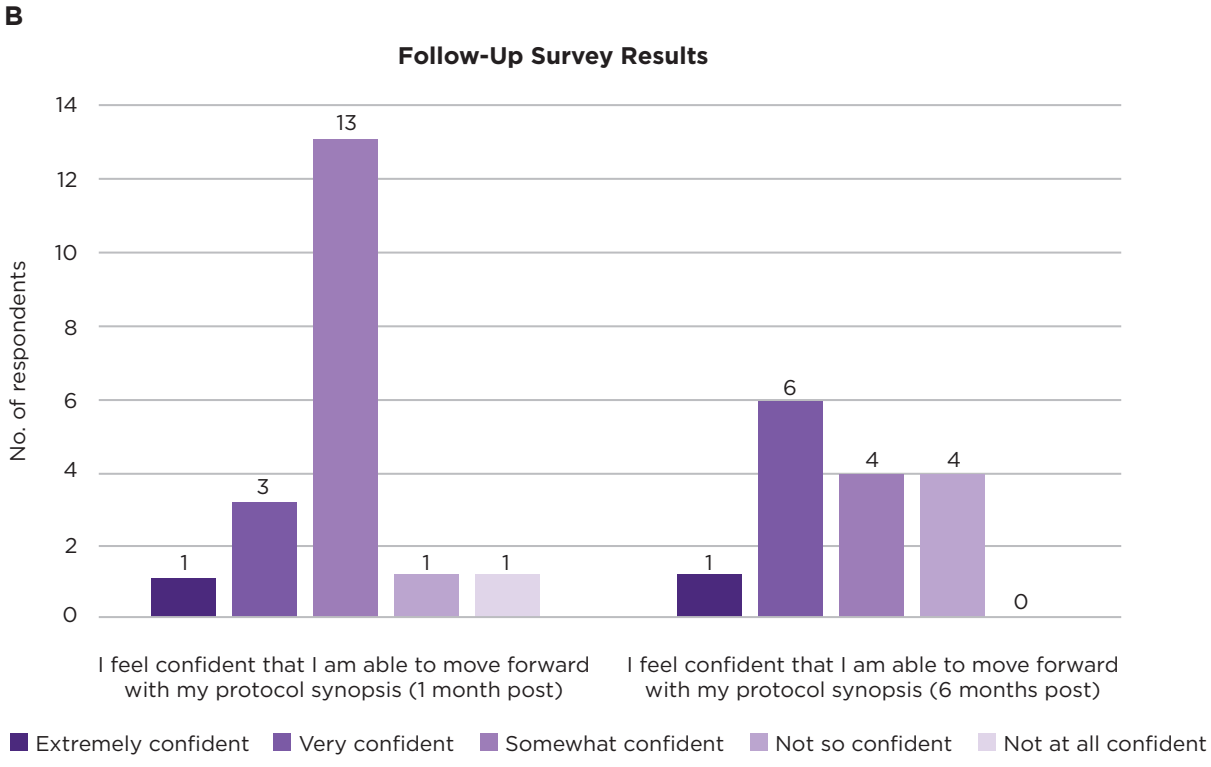


Figure 2. Follow-up survey results. (A) Percentage of participants who reported reviewing their protocol synopsis with their mentor on the 1-month follow-up survey (*n* = 19). (B) Follow-up survey results at 1 and 6 months post-course inquiring how confident participants felt in moving forward with their protocol synopsis (1 month *n* = 19, 6 months *n* = 15). (C) Follow-up survey results at 6 months post-course evaluating participant agreement that this course assisted them to become more confident in becoming a sub-investigator (sub-I) and principal investigator (PI) (*n* = 15).

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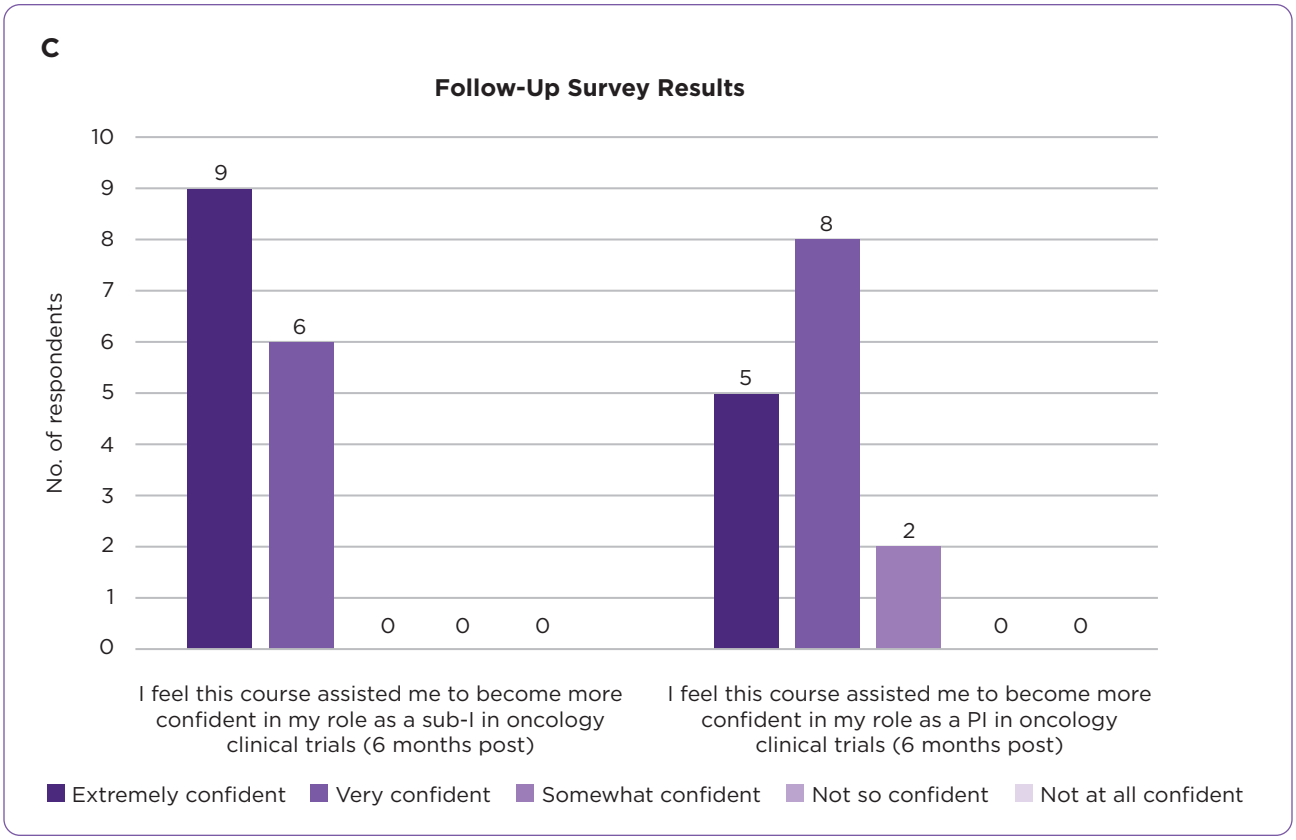

Figure 2. Follow-up survey results (continued). (A) Percentage of participants who reported reviewing their protocol synopsis with their mentor on the 1-month follow-up survey (n = 19). (B) Follow-up survey results at 1 and 6 months post-course inquiring how confident participants felt in moving forward with their protocol synopsis (1 month n = 19, 6 months n = 15). (C) Follow-up survey results at 6 months post-course evaluating participant agreement that this course assisted them to become more confident in becoming a sub-investigator (sub-I) and principal investigator (PI) (n = 15).

up survey, 91% (19/21) participants responded and 74% (14/19) reflected positively on the course overall. When asked if they had reviewed the drafted protocol synopsis with their mentor 63% (12/19) reported they had (Figure 2A), with the majority (17/19) feeling at least somewhat confident that they were able to move forward with their protocol synopsis (Figure 2B). At the 6-month follow-up survey, this trend continued with the majority (11/15) feeling at least somewhat confident that they can continue moving forward with their protocol synopsis (Figure 2B). When asked how strongly they believed this course assisted them to become more confident in their role as PIs and sub-Is in oncology clinical trials, 100% (15/15) agreed or strongly agreed for sub-Is while 87% (13/15) agreed/strongly agreed for PI (Figure 2C). All participants (100%) would recommend this course to their colleagues.

CONCLUSION

Oncology advanced practitioners are both capable and interested in taking on the role of PIs and sub-Is in clinical research. However, additional mentoring and education are needed for optimal success in these roles. The reported course developed at HRI provided a structure and hands-on education for OAPs to grow the advanced skills required for protocol development and clinical trial leadership. Measurable improvements in participants' knowledge of PI and sub-I activities and confidence in protocol writing were found, which we believe will ultimately lead to more OAP participation in clinical trials and support the advancement of novel therapeutics.

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Disclosure

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