



Cancer Clinical Trials Office (CCTO) Orientation Course Reduce Insufficiencies Among Study Coordinators

Authors: Katrina Croghan, M.S., CCRP, Gwen Boe, M.A.N, R.N., Jade Zbacnik, Amanda J Youssef, M.S., Adam Holland M.S., Grzegorz Nowakowski, MD, Angela Fritsche, MPA
Comprehensive Cancer Center, Mayo Clinic

BACKGROUND

The Mayo Clinic Comprehensive Cancer Center (MCCCC) CCTO serves the clinical investigators and research participants across the academic medical centers in Arizona (ARZ), Florida (FLA), Mayo Clinic Health System (MCHS), and Rochester (RST).

The complexity and geographic distribution of staff has led to a lack of standardization among training programs and available resources. While numerous training materials and onboarding processes were developed, the utilization of these resources by CCTO staff was inconsistent and ineffective.

In 2019, an RST MCCCC All Staff Survey indicated 33% of study coordinator (SC) staff requested a standardized training for new hires. This led to the development of the CCTO SC Orientation in October 2020.

TABLE 1: General topic development for CCTO Orientation course

	Topic		
	Monday	Wednesday	Friday
Week 1	Course Introduction / Review of commonly used resources within the Cancer Center	Overview of Protocol Types within the Cancer Center	Case Report Forms / Source Docs
Week 2	Informed Consent / ROI	Eligibility / Demographics / Screen Failures	Modification / Reconsent / Withdrawals
Week 3	EPIC - inbaskets, secure chat, local lab orders	Beacon Treatment Plans	Inpatient and Team communications
Week 4	BAP - Kit builds, kit requests	BAP - collection, processing, shipping	Trial Start-up / Logistics / RPS study hand-offs
Week 5	AE Abstraction and documentation / CTCAE	SAEs - documentation and reporting	Deviations
Week 6	Research Reimbursements/ Remuneration and RBITS	Data Entry, Data Queries	Quality Checks, Audits, Continuing Reviews

GOALS

Implement a MCCCC New Hires Orientation course that would help:

- Establish expectations and resources available for study teams
- Address the decline in retention
- Increase familiarity with resources among SC staff

SOLUTIONS AND METHODS

ENTERPRISE ASSESSMENTS

A 10-day Orientation to Research course, completed by all study teams new to research.

Competency exam, completed by all SCs at the one-year mark.

CCTO COURSE SETUP

The Orientation course occurs over 6-weeks, 3-times/week in 2-hour intervals.

Covers general topics relating to conducting studies within the CCTO and expands specifically on the requirements and resources available to staff, along with providing examples and walkthrough scenarios.

Resources and Course Materials housed in the CCTO Quality Management System (QMS), which are sustained, and maintained by the MCCCC Quality Management Coordinators.

FEEDBACK MECHANISM

Established to capture information from the new hires pre and post CCTO Orientation course to help identify educational and procedural gaps in the course and/or resources.

The gaps would then be fed back to the CCTO Leadership teams to help establish and revise resources and educational material as needed.

Feedback Mechanism includes:

- Chat cohort communication- where anyone can ask questions and the preceptors and supervisors help address in real-time
- Included Pre- and post-orientation anonymously REDCap surveys.
- Post orientation assessments at 6-week and 6-months via one-on-one sessions between the Preceptor and attendee.
- 30-question review sent to each attendee at the 6-week mark.

OUTCOMES

DEMOGRAPHICS

- As of March 2023, the course has completed 12 cohorts with ~130 attendees over multiple units within MCCCC and beyond.
- The post-assessment data revealed on average, the attendees feel comfortable with the resources available.
- They reach out to CCTO team staff with questions, and concerns. This can also be illustrated in our quality review findings in RST and MCHS, where there has been a decline in major findings across delayed SAE reporting and deviation timeline reporting.

FIGURE 1

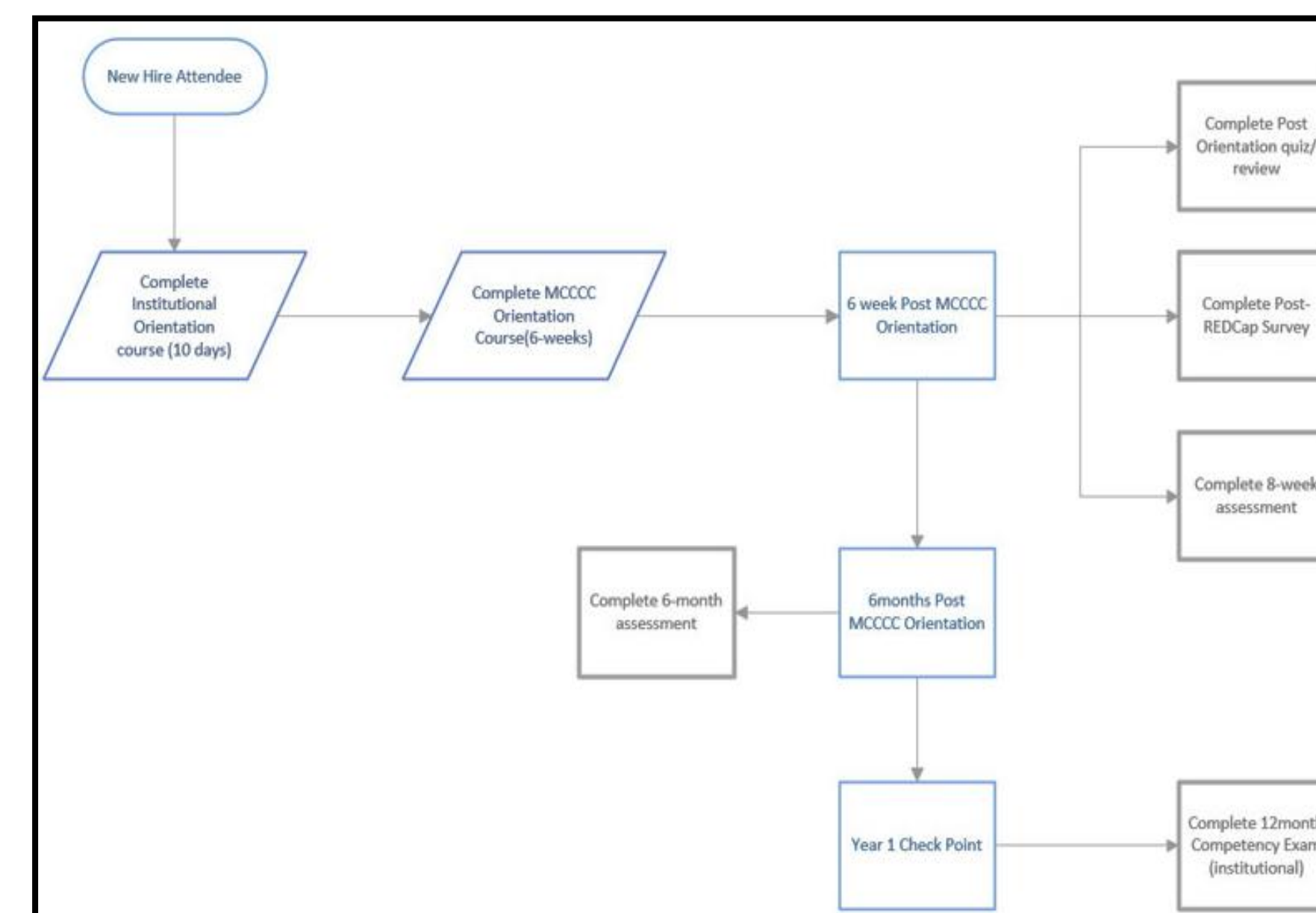


Figure 1 represents the CCTO new Hires Orientation course assessment flow

TABLE 2: Post Survey Confirmation regarding the Preceptors and the Orientation Course

	Survey score (1-5) (see footnotes for key)		
	Preceptors presented constant information	I had opportunities to ask questions and speak up	Preceptors were accommodating to the individual needs
Average (n=79)	4.74	4.94	4.83
Standard Deviation	0.47	0.30	0.37

Footnotes:

- N=79 included the 65 SC required attendees and a few additional members who wanted to participate in the post-assessments.
- Table 1 Key:
 - 1 & 2 = Strongly disagree/Disagree with the statement
 - 3 = Neutral
 - 4 & 5 = Agree/Strongly agree with the statement.

LESSONS LEARNED

Orientation has become an effective tool and resource for attendees.

A focus on establishing continuous resources to help shift seasoned staff mind set on new and updated Standard Operating Procedures (SOP) is vital.

FUTURE DIRECTION

Focus on education will now turn to:

- Expanding to ARZ, FLA and MCHS where possible
- Continuous education resources and materials for all SC staff using the Quality Management System (QMS)- implementation pending June 2023
- Mentor Training to help guide mentors through the mentorship process
- Disease Education

ACKNOWLEDGMENT

Special thank you to the Rochester study coordination teams and supervisors for participating and precepting the orientation course since cohort 1 (October 2020). In addition, a huge thank you to MCCCC Leadership and Quality Management System (QMS) for all the support and resources to keep the course moving forward.

This work was funded by the Mayo Clinic Comprehensive Cancer Center.