Improving Clinical Research Coordinator Performance Through Structured Skills-Based Training and Assessment

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BACKGROUND

The UF Health Cancer Institute (UFHCI) Clinical Research Office (CRO) is responsible for the development, regulatory maintenance, clinical conduct, and oversight of clinical research. In 2020, we implemented a research-specific, electronic learning management system (eLMS)-based orientation curriculum with the goal of improving overall job performance, job confidence, and staff retention. This orientation program provides comprehensive and consistent research-focused education for all new research staff but lacks the targeted development of essential role-specific job skills and standardized measurements of staff performance at the 3 and 6-month probationary review required for effective onboarding.

GOALS

- Provide skill-based training specific to the functional needs of new Clinical Research Coordinators (CRC).
- Develop and implement skills-based rubric to facilitate consistent assessment of new CRC functional development.

Intro to Clinical Trials & Oncology	• **CTMS Infrastructure Review** • **Shared Resource Review:** Microsoft Teams, SharePoint, Veeva • **Clinical Structure Overview:** Hospitals, Outpatient Clinics, Labs, Radiology
Regulatory & Essential Documents	• **Protocol Navigation Review**: Organizational tools (checklists, Fast Facts, IP Info Sheets etc.), Training Processes • **Delegation of Authority**: Master DOA, Study Specific Memos, Supplemental Memos • **IRB Submission and Approval**: Selecting IRB of Record, Reconsent requirements • **Regulatory Focused CTMS Review:** Approval documentation (SRMC, IRB, Ancillary Committee), Status, Task Lists, Staff List & Roles
Clinical Operations and Laboratory Training	• **EMR**: Study Coordinator Console, Schedule Review, Communication Tools, Research Processes (Study Maintenance, Beacon, Order Management, TP Management, Scheduling) • **Clinical Skills:** ECG Training, Phlebotomy, Specimen Tracking, Ancillary Team Communication & Contacts • **DSG Specific Training:** Disease Specific Training, Genetic Reports, Identifying Lines of Therapy, Current Treatment Practices
Subject Management	• **Informed Consent & Enrollment**: Process and Execution, Documentation, eConsent, Screening, Eligibility Review • **Safety and Data Collection:** Data Collection Workshop (Medhx, AEs, ConMeds, Prior Therapies), SAE Reporting, CTCAE, RECIST 1.1 • **Subject Focused CTMS Review:** Calendars, Visit Check-In, Deviation Reporting, SAE Console, Financial Events
Compliance Training	• **Auditing & Monitoring:** External Monitoring (Onsite vs. Remove; EMR Access Requests), Internal Auditing (Types of Audits, Audit Manual / Checklist), Internal Monitoring, Cooperative Group Audits, FDA Audits • **Data Integrity:** ALCOA+, Source Documentation, eSignatures, eBinder Management, PI Oversight • **Site SOP Review**
Billing Compliance	• **Hospital Billing:** OnCore-EPIC Billing Interface, EPIC Timeline Application & Management, EPIC Billing Review, Correcting Billing Errors • **Clinical Research Office Finance**: Sponsor Billing, Invoicing, Financial Audit Process, Data Entry Reminders • **Finance Focused CTMS Review:** Subject Visit Check-Ins, Financial Event Entry

Functional Area	3-Month Expectation	6-Month Expectation (Probationary Review)	12-Month Expectation
Protocol Interpretation and Management	Demonstrates ability access the current version of assigned protocols and other key study documents in the CTMS. Can identify and locate key sections in each protocol including: • Objectives • Patient eligibility criteria, • Treatment plan • Schedule of events • Safety monitoring and reporting requirements With assistance can connect key objectives with the corresponding endpoints and associated study procedures. In conjunction with the unit manager or senior staff member: • Attends Sponsor and other protocol meetings (DSG, DISC, SRMC etc.) as assigned • Can identify and describe their role in each meeting (e.g. observer for information purposes only, primary site representative to attest to and report on site conduct and work, SME to answer question and advise as needed, etc.	Independently applies protocol to subject management for their currently assigned studies as demonstrated by: • Identifies study procedures required for safety monitoring vs research / data only procedures • Can create a subject visit plan or checklist utilizing the SOE and treatment plan for assigned studies • Locate and with assistance, accurately interpret sections of the protocol required to manage patient care (e.g. dose reduction / dose hold requirements, DLT assessments etc.) • Routinely refers to assigned protocols to answer study specific questions before requesting assistance With preparation, educates patients, clinical staff and co-workers on protocol requirements and processes. Under the supervision of the Unit Manager or senior staff member: • Attends and participates in Sponsor and other protocol meetings (DSG, DISC, SRMC etc.) • Prepares adequately and participates according to their role in all protocol meetings • Communicates w/ Manager and/or team members in advance to arrange coverage for any meetings that they cannot attend	Independently applies protocol to subject management across multiple studies (cross coverage) as demonstrated by: • Utilizes the protocol to plan for and manage participant study visits • Independently interprets the protocol as needed to manage patient care (e.g. dose reduction / dose hold requirements). • References protocols to help answer protocol specific questions as they arise, and collaborate with the clinical care team to manage patient care Serves as protocol SME and collaborates with the clinical care team to ensure comprehensive protocol compliance. Independently attends and participates in all assigned Sponsor and other protocol meetings (DSG, DISC, SRMC etc.), requiring only periodic or "as needed" support from Unit Manager or Senior Staff Independently arranges coverage for any meetings that they cannot attend.

METHODS

An in-person, nine-week intensive "bootcamp"-style training program specific to the CRC was developed as companion training to the existing online orientation curriculum to assist with functional skill development. The in-person, classroom style forum encouraged peer coaching and learning, and reinforced the collaborative work model practiced by clinical teams in their day-to-day practice. This training utilized the previously developed concept-based orientation, identifying and teaching the practical skills that accompany each of the six topical categories essential to the conduct of clinical research. Training included direct instruction from subject matter experts and senior coordinating staff, data collection workshops, and peer coaching. A corresponding skills-based rubric was developed to establish expectations for demonstration of key skills for new CRCs at 3, 6 and 12 months, to correspond with established UF Engaged staff review timepoints.

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OUTCOMES

From August 2025 to present, 11 new staff members with diverse professional and educational backgrounds were hired into 3 separate clinical teams and onboarded using the dual eLMS-based curriculum and skills-based "bootcamp" training sessions. All staff were assessed according to the skills-based rubric with 72% of the initial cohort completing all training in the required period and successfully passing the probationary period by meeting expectations set forth at the 3- and 6-month check-in. The individuals who did not meet the 6-month expectations were granted a 3-month extension and individual training plans with SMART goals and resource planning were developed to ensure accountability from both the staff member and manager in supporting the individual's continued development.

LESSONS LEARNED AND FUTURE DIRECTIONS

Establishing standardized expectations for new staff and providing specific assessment tools for onboarding managers has improved alignment among the clinical management team, supported new managers in objectively establishing and clearly communicating expectations and goals, and improved staff and manager accountability to the onboarding process. The introduction of the skills-based rubric enables earlier identification of learning gaps, workload barriers, and support needs, facilitating proactive intervention, and has proved essential in preventing avoidable performance issues. Additional work is being done to update the e-learning concept orientation to ensure clear alignment with the skills-based training and assessment rubric, and future plans include creating similar framework for other CRO divisions and around continued professional development for staff beyond the first year of practice to support ongoing growth and advancement-based rubric.