Association of American Cancer Institutes
Clinical Research Innovation

AACI CRI Education and Operations Subcommittee
Onboarding and Retaining Clinical Research Staff - Recommendations and Benchmarks
December 2021

Overview

The AACI CRI Education and Operations Subcommittee, consisting of sixteen cancer centers, has met every other month since January 2021 to gather best practices for onboarding new clinical trials office (CTO) staff and retraining existing staff. In reviewing training programs, the committee saw a need to address centers' inability to retain staff and to identify ways to improve retention.

As part of the project, recommendations were made, and benchmarks set for clinic CTO training programs. Due to the scope of the project, the committee suggested breaking it down into three parts to facilitate data collection, with each cancer center reporting on the following:

- Descriptions of CTO roles
- Training curriculum for onboarding each position
- Expected timeframes for role-based training and outcomes

Fourteen cancer centers participated in the project *(see attachment 1)*. Data collection started with each center identifying roles and responsibilities for each position within the CTO, pre-requisites for new staff, and expectations for existing staff seeking advancement in career ladder programs.

In the second part of the project, each center reported general training details, e.g., who administered the training, length of training, and courses offered for new employees.

For the third part of the project, each center provided information on specific classes offered for general cancer center onboarding and CTO training, as well as when "refresher" classes were offered to current employees.

The data showed that most centers had similar structures in place despite differences in job titles. In some instances, responsibilities were shared between two roles, such as a clinical research specialist doing data submission and other research related duties. Many cancer centers reported high rates of turnover during the pandemic, with centers losing nurses and experienced trial coordinators to other cancer centers, industry, and contract research organizations (CRO). Without a career ladder or institutional policies for salary adjustments, centers were unable to meet salary demands for staff considering industry positions.

Regarding training, most centers' training programs had similar lengths and course offerings *(see attachment 2 for classes offered at each center)*. One observed difference was that not all centers have a dedicated educator role or training department. Eight of the 14 (57%) cancer centers surveyed had a position within their CTO responsible for training new hires and reassigned staff. A few centers have recently created a position, and/or have a general education department. Two of the 14 (13%) centers do not have a dedicated educator position but are planning to create one or hire an educator in the future.

Recommendations and Benchmarks

Retention

- The COVID-19 pandemic forced cancer centers to permit remote work and it has now become the norm for most centers. It is recommended that most cancer centers continue to offer remote or hybrid work options to enhance work/life balance and provide advantages such as reductions in commuting times and transportation expenses.
- Cancer centers should review and revise their current staff positions annually to ensure that salaries are competitive with the oncology industry and minimize staff turnover. Consider pay increases to promote retention and to better align salaries with market analysis.
- Create tiers based on job responsibilities to provide progressive management levels for staff seeking advancement opportunities or as challenges to experienced staff.

Training

- Utilize a dedicated educator role within the cancer center CTO to create a positive impact on training, onboarding, and continuing education. Such a role can enable the CTO to assess levels of competency among the newly hired and existing employees and to offer refresher courses where needed.
- Have in place an organized training curriculum to provide rapid and effective training to counter staff turnover.
- Provide leadership training to staff members who are promoted within the career ladder system to address the gap in leadership and management skills.

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Attachment 1 - 2021 AACI CRI Education and Operations Subcommittee who Participated

Alexandra "Sandy" Annis, BA, CCRP
Senior Director, Clinical Operations - CTO
Kansas University Cancer Center

Dina Aziz, MSHS
Executive Director, VP, Clinical Research Administration
The University of Texas MD Anderson Cancer Center

Wendy Bloomer, PhD, CCRP
Research Practice Manager
Duke Cancer Institute, Duke University Medical Center

Deidre L. Cleary, RN, BSN, CCRC
Senior Director, Clinical Research Services
UPMC Hillman Cancer Center

Megan Farmer, MS
Co-Director, Clinical Research Management
Wake Forest Baptist Comprehensive Cancer Center

Chloe Fournier
Associate Director, Compliance and Training
Duke Cancer Institute, Duke University Medical Center

Catherine Gregor
Director, Clinical Research Administration
Vanderbilt-Ingram Cancer Center

Brenda Hann, RN, MBA
Director, Clinical Operations
Stanford Cancer Institute

Christine Jerome
Senior Director, Quality Assurance & Process Improvement Unit
Sidney Kimmel Cancer Center at Jefferson Health

Fyalon Kerr, CCRP
Education and Quality Assurance Coordinator
Indiana University Melvin and Bren Simon Comprehensive Cancer Center

Rachel Kingsford, MS, CCRP
Training & Mentorship Manager
Clinical Research Administration
Huntsman Cancer Institute, University of Utah

Erin E. Lynch, MS, CCRP
Research Operations Manager
Regulatory & Compliance
Dartmouth-Hitchcock Norris Cotton Cancer Center

Sarah Osipowicz, MSEd, CCRP
Director, Protocol Support Unit
Sidney Kimmel Cancer Center at Jefferson Health

Cary Passaglia, CCRP
Administrative Director, Clinical Trials
Robert H. Lurie Comprehensive Cancer Center of Northwestern University

Helen Peck, RN, MA, OCN, CCRP
Executive Director, Clinical Trials Office
Wilmot Cancer Institute

Kim Nguyen
Assistant Director of Regulatory Affairs
Winship Cancer Institute

UPMC Hillman Cancer Center Job Responsibilities & Qualifications

Title of Position (e.g. study coordinator, research nurse vs. non-nurse, regulatory, pre-award finance, post-award finance, data analyst, manager, etc.)	**Main Responsibilities** (highlight 2 or 3 responsibilities of the role)	**Pre-requisites for Hiring** (e.g., degree, prior work experience, medical terminology, prior oncology experience, etc.)	**Career Ladder** (Yes or No)	**Comments**
Research Associate I	Coordinate SIV, PSVs, monitoring visits, data entry, follow all requirements for GCP/Regulations, prepare lab kits as designated by protocol	HS diploma and 4 years research experience in clinical research ***or*** BS in health sciences	Yes	Entry level position
Research Associate II	Prepare for and attend research biopsies, lead monitoring visit, coordinate data collection for data locks, maintain disease center lists	BS in health sciences, 3 years exp of which 18 months must be in clinical oncology research	Yes	
Research Associate, Senior	Assist in training new staff, assist with internal data quality reviews	BS in heath science, 4 years of exp, 18 months must be in clinical oncology research, clinical certification preferred	Yes	
Research Associate, Supervisor	Facilitate SIV, PSV, monitoring visits, audits, data entry, assists in screening process, performs 2nd checks of eligibility, supervise query resolution statistics and patient tracking sheets	BS in health sciences, 6 years oncology/clinical research exp, or MS and 5 years of research exp of which 3 must be in clinical oncology, clinical research certification is required	Yes	
Research Coordinator	Follow appropriate research policies and procedures to recruit and consent patients, collect and enter quality trial related data, evaluate policy/procedures for effectiveness, assist with clinical coordinating tasks delegated by the management team	BS degree, MS preferred, experience in process evaluation, coordination of multiple aspects of research projects	No	
Clinical Research Coordinator I	Consent patients, adhere to protocol/regulatory/GCP standards, facilitate the effective conduct of research	RN required, AS/BS preferred, 2 years research OR 2 years of nursing exp	Yes	Entry Level Position
Clinical Research Coordinator II	Utilizes a variety of strategies to enhance recruitment, identifies opportunity for quality improvement to colleagues and management, actively participates in quality improvement efforts	BS preferred, RN required and 3 years of clinical research (oncology preferred) or nursing experience	Yes	
Lead Clinical Research Coordinator	Assists PI in reviewing new procedures/amendments related to complex protocols, primary liaison for complex studies and IITs, develops study implementation materials for complex trials and conducts in-service education	BS preferred; RN required with 4 year relevant professional experience 2 years with preferred degree	Yes	

UPMC Hillman Cancer Center Job Responsibilities & Qualifications

Clinical Research Supervisor	Responsible for day-to-day operations of smaller disease centers, perform annual evaluations for staff, mentor professional development, participate in hiring decisions and delegating tasks, continue to conduct all aspects of clinical research coordinator responsibilities	BS preferred, certification preferred, RN required, 5 years of relevant exp preferably in oncology setting or 3-year clinical research experience preferrable in oncology with advanced nursing degree, solid/strong performance review	Yes	
Regulatory Specialist	Responsible for protocol start up and maintenance. Liaise with sponsors, investigators, and team members. Maintain an organized and accessible regulatory file for site auditing/monitoring visits per SOP	BS degree, knowledge of clinical trials regulation or 1+ years exp in drug development, regulatory, and operations.	Yes	Entry Level
Regulatory Specialist - Senior	Performs tasks with minimal supervision. Uses a variety of resources and strategies to manage protocols independently. Serve as a mentor/trainer to entry level regulatory staff	BS degree, knowledge of clinical trial regulations or 2+ years of research experience in drug development, regulatory, and operations.	Yes	
Regulatory Specialist – Supervisor	Designs new processes and procedures within the regulatory/clinical department, develop protocol required documents and coordinate protocol implementation as needed, ensures research documentation is comprehensive and facilitates protocol compliance, functions as a direct supervisor for regulatory and/or clinical personnel	BS degree with 5 years of experience required, must possess excellent detail oriented, outstanding organization and time management skills to complete several projects/tasks simultaneously, Certification Preferred	Yes	Management
Clinical Research Manager	Responsible for day-to-day operations for a complex disease center including staff oversight, conducts recruitment and evaluation, work assignment, oversee timely activation and execution of protocols	BS degree nursing, biomedical, or business, Masters preferred. 7 years professional experience, 5 years of clinical research experience with preferred degree, Certification Required		
Senior Clinical Research Manager	Conduct yearly assessments of operations/issues and utilizes data from other organizational assessments and surveys to contribute to prioritize the establishment of quality, cost, and service goals of the organization. Lead multiple disease centers	BS degree required, BSN or master's degree preferred, 3 years of Clinical Oncology Research Management Experience required, 10 years of professional experience, 8 years of clinical research experience with preferred degree		

Winthrop P Rockefeller Cancer Institute Job Responsibilities & Qualifications

Title of Position (e.g. study coordinator, research nurse vs. non-nurse, regulatory, pre-award finance, post-award finance, data analyst, manager, etc.)	**Main Responsibilities** (highlight 2 or 3 responsibilities of the role)	**Pre-requisites for Hiring** (e.g., degree, prior work experience, medical terminology, prior oncology experience, etc.)	**Career Ladder** (Yes or No)	**Comments**
Regulatory Specialist	All committee approvals, requirements for opening studies and maintaining study approvals	**Level 1** – Bachelor's degree plus 3 years general research experience OR high school plus 7 years research experience **Level 2** - Bachelor's degree plus 3 years of general research experience OR high school plus 7 years research experience with demonstrated proficiency in one of the strategic areas **Level 3** – all of above plus 5 years clinical research experience with demonstrated proficiency, CCRP required	Yes	**Level 1 – Level 3** career ladder, needs refinement Staff are maxed out at level 3 with no growth from there. Some lower-level staff who don't have 5 years' experience yet but operate as a level 3 HR hurdles with refining, understanding terminology No FDA interactions, those are done through a centralized office on campus –desire to bring in house.
Regulatory Team Lead	Director leadership over team, help with workload, supervisory oversight	5 years clinical research experience, 3 years oncology research, 1 supervisory or project management CCRP required	No	See leadership skills in people with less than 5 years of clinical research experience, struggle with HR
Finance Administrator	Pre-award and post-award financial processes, include budget development, budget negotiation, financial processes	Bachelor's degree plus 3 years of finance experience	No	No separation of pre-award and post-award however this is widely needed. Position level ranked way too low – salary level too low. Title misunderstood. Can't get research experience eligible, etc.
Finance Team Lead	Leads all finance team	Bachelor's degree plus 5 years finance experience	No	
Research Nurse	All clinical responsibilities: consent, Adverse events, etc.	Bachelor's degree plus 3 years of nursing or research experience, RN	No	Need career ladder, salary too low for hiring a nurse
Research Nurse Team Lead	Leads all RNs	Bachelor's degree, RN, 5 years clinical research experience to include 3 years of oncology experience	No	
Study Coordinator (CRA), non-nurse		**Level 1** – Bachelor's degree plus 3 years of general research experience or high school plus 7 years of research experience (lab or clinical) **Level 2** – Bachelor's degree plus 3 years of general experience or high school diploma plus 7 years of research experience with	Yes	Problems with having people be eligible to apply for position level 1 – requires 3 years' experience. Difficulty with HR understanding needs of candidates.

Winthrop P Rockefeller Cancer Institute Job Responsibilities & Qualifications

		demonstrated proficiency in one or more of the following areas relevant to oncology trials: study planning/development, study coordination/management and data collection. **Level 3** – bachelor's degree plus 5 years clinical research experience (or high school diploma plus requirements above plus 5 years clinical research experience) – CCRP required for level 3		
Study Coordinator (CRA) Team Lead	Lead a team of CRAs	Bachelor's degree or HS plus 9 years' experience Plus 5 years clinical research experience to include 3 years oncology research experience; CCRP or equivalent required	No	4 teams right now – want disease breakdown, managers
Assistant Director Regulatory and Finance	Leads Regulatory and Finance Unit	Bachelor's degree, 8 years research experience to include 3 years oncology experience and 1 year supervisory	No	No consistency among PCQs
Assistant Director clinical Operations	1 AD for Solid Tumors, 1 AD for Hematologic Malignancies	Bachelor's degree plus 10 years clinical research experience, 6 years oncology, 4 years supervisory	No	
Program Manager	Medicare Coverage Analysis, Liaison with disease teams, new studies	Bachelor's degree, five years of related experience, coding experience	No	
Lab Support Technician	Handles all research specimens – processes, shipping and handling	3-5 years lab experience	No	Needs career ladder within team, base level pays comparable to regular blood draw people, but position should be ranked higher – more complex management.
Executive Director, CTO	Leads all CTO operations	Bachelor's Degree plus 7 years in management and administration of a clinical research program, CCRP required, Master's degree preferred	No	

Robert H. Lurie Comprehensive Cancer Center Job Responsibilities & Qualifications

Title of Position (e.g. study coordinator, research nurse vs. non-nurse, regulatory, pre-award finance, post-award finance, data analyst, manager, etc.)	**Main Responsibilities** (highlight 2 or 3 responsibilities of the role)	**Pre-requisites for Hiring** (e.g., degree, prior work experience, medical terminology, prior oncology experience, etc.)	**Career Ladder** (Yes or No)	**Comments**
Data Assistant	• Responsible for the compilation of all data for clinical trials managed by the CTO. Manages project data including extraction, entering, processing, accuracy, analysis and evaluation of data ensuring that results meet project information and deliverable objectives. • Assists with monitoring visits and site audits	• A high school diploma or equivalent is required. • 2 years' data entry or similar experience is required. • Ability to understand complex pathology data and cancer treatment regimens and their toxicity. • Medical Terminology	Yes: Senior Data Assistant Data Team Lead Coordination etc.	
Senior Data Assistant/Team Leads	• Serves as a resource to staff regarding data entry, maintenance, and results. • Coordinates incoming data for accuracy and integrity, assists with complex data preparation, analyzes data, and creates reports. • Ensures associated administrative tasks such as documentation, editing of code books and manuals, etc. are completed. • Responsible for the compilation of all data for clinical trials managed by the CTO. • Team Leads head process improvement projects and serve as mentors to junior Data Assistants	• Successful completion of a full 4-year course of study in an accredited college or university leading to a bachelor's or higher degree; OR appropriate combination of education and experience. • Experience in data management in a health field, exposure to cancer clinical trials. 1-2 years' experience in cancer research • Computer literate in basic software, internet use, and cancer-related databases.	Yes: Coordination, Regulatory or QA Track	
Clinical Research Coordinator	• Leads execution & control of a biomedical research study. • Manages and ensures completion of study activities per protocol. • Collaborates with nursing staff and Principal Investigator (PI) ascertains pretreatment & eligibility requirements; interviews participants & obtains social & medical histories; based on results determines & registers participants with appropriate sponsors; completes informed consent; determines & organizes patient's treatment and test schedules. • Manages conduct of experimental tests & procedures. Closely monitors & documents patient's adverse events; partners with nursing	• Successful completion of a full 4-year course of study in an accredited college or university leading to a bachelor's or higher degree in a major such as social or health science or related; OR appropriate combination of education and experience and 2 years' research study or other relevant experience required; OR • Successful completion of a full course of study in an accredited college or university leading to a master's or higher degree in a major such as social or health science or related; OR appropriate combination of education and experience and 1 year research study or other relevant experience.	Yes: Senior CRC Clinical Team Lead Project Manager Clinical Manager	

Robert H. Lurie Comprehensive Cancer Center Job Responsibilities & Qualifications

	staff in modifying dosages, tests & treatment schedule.	Supervisory or project management experience required.		
Senior CRC/Team Leads	• Leads execution & control of a biomedical research study. • Manages and ensures completion of study activities per protocol. • Collaborates with nursing staff and Principal Investigator (PI) ascertains pretreatment & eligibility requirements; interviews participants & obtains social & medical histories; based on results determines & registers participants with appropriate sponsors; completes informed consent; determines & organizes patient's treatment and test schedules. • Manages conduct of experimental tests & procedures. Closely monitors & documents patient's adverse events; partners with nursing staff in modifying dosages, tests & treatment schedule • Involved in Staff Training, serves as a Mentor for junior staff • Involved in process improvement initiatives	• Successful completion of a full 4-year course of study in an accredited college or university leading to a bachelor's or higher degree; OR appropriate combination of education and experience. • 2 years prior experience coordinating or monitoring therapeutic clinical trials. • Experience in staff education and training activities.	Yes: Project Management Clinical Operation Manager	
Clinical Research Project Manager	We have several different positions under the Project Management umbrella including: • Study Start Up Associate • NCTN Program Manager • Affiliate Operations • Internal Auditor • Staffing & Education	• Successful completion of a full 4-year course of study in an accredited college or university leading to a bachelor's or higher degree in a major such as social or health science or related; OR appropriate combination of education and experience and 5 years' research study or other relevant experience required • At least 5 years of experience in clinical research	Yes: Management	
Regulatory Coordinator	• Coordinates and guides the review and approval process of all research activities associated with clinical research studies involving human subjects • Acts as liaison between research staff (PI, faculty, nurses, technicians, etc.), and internal/external regulatory and oversight groups (NU's IRB, sponsors (NIH, industry), government agencies (FDA), etc.)	• Successful completion of a full 4-year course of study in an accredited college or university leading to a bachelor's or higher degree in a major such as computer science, information technology, or related; OR appropriate combination of education and experience.	Yes: Senior Regulatory Coord. Regulatory Manager	

Robert H. Lurie Comprehensive Cancer Center Job Responsibilities & Qualifications

	• Guides and coordinates all associated submission, documentation, and reporting processes (new study applications, renewals, revisions, modifications, amendments, adverse events, safety reports, close-out, etc.) recommending alternatives to ensure compliance and approval.	• Knowledge of oncology terminology and staging; General knowledge of protocol design.		
Senior Regulatory Coordinator	In addition to the responsibilities listed above for Regulatory Coordinator, Senior RC's: • Provides guidance and training to junior staff and research staff to ensure compliance with complex, highly specialized rules and regulations associated with clinical research studies and trials involving human subjects. • Serves as a resource to the clinical research office staff on regulatory concepts. • Researches new and updated rules and regulations associated with clinical research studies and trials involving human subjects.	• Successful completion of a full 4-year course of study in an accredited college or university leading to a bachelor's or higher degree; OR appropriate combination of education and experience. • Three years of work experience in a regulatory and/or medical research environment having developed a strong working knowledge of clinical research protocols or other relevant experience required	Yes: Regulatory Operations Manager	
Entry Quality Assurance Monitor	• Utilizes multiple quantitative and qualitative datasets from a variety of sources and interprets results using various techniques, ranging from simple data aggregation via statistical analysis to complex data mining • Compiles reports, charts, and tables based on established statistical methods. • Monitors study performance, analyzes and review results and supervises development & implementation of new protocols	• Successful completion of a full 4-year course of study in an accredited college or university leading to a bachelor's or higher degree; OR appropriate combination of education and experience. • 2 years prior experience coordinating or monitoring therapeutic clinical trials. • Strong regulatory background as demonstrated by knowledge of the Code of Federal Regulations and Good Clinical Practice guidelines.	Yes: Senior QAM QAM Team Lead QA Manager	
Senior Quality Assurance Monitor / Team Leads	In addition to the responsibilities of Entry QA's, Senior QA's: • Provide mentorship and training to QA staff • Work with programmers for improvements in internal data management system • Involved in process improvement projects • Monitor the more complex trials	• Successful completion of a full 4-year course of study in an accredited college or university leading to a bachelor's or higher degree; OR appropriate combination of education and experience. • 4 years prior experience coordinating or monitoring therapeutic clinical trials. • Strong regulatory background as demonstrated by knowledge of the Code of	Yes: Quality Assurance Manager	

Robert H. Lurie Comprehensive Cancer Center Job Responsibilities & Qualifications

		Federal Regulations and Good Clinical Practice guidelines.		
Clinical Research Nurse	• Screens patients for eligibility for inclusion into the studies; Provide direct care to research patients, including drug administration, lab draws, coordination of appointments, follow-up and management of side effects, identification of home care needs. • Oversee care to assure protocol adherence is maintained by staff, serve internally as a resource for nursing (outpatient, inpatient, home care), medical staff and CRO staff • Involved in providing staff education as needed for participation in particular research activities; Provides staff education on general clinical trial information; Assist in orientation of new staff members to CRO; Provides patient education in daily practice	• Current license as Registered Professional Nurse in State of Illinois • BSN with 3 years clinical practice • Clinical Research Coordinator certification (within 6 months of eligibility) • Involved in external professional organizations (e.g. Oncology Nursing Society, nursing committee co-operative groups) and obtains and maintains OCN certification within 6 months of eligibility if not already certified.	No	
Clinical/Reg/QA/ Manager	• Oversees day-to-day operations including identifying & securing needed resources; creating, implementing, monitoring, & updating project plans; facilitating meetings with appropriate parties; tracking tasks/deliverables to ensure timelines, milestones &/or goals are attained; monitoring & reporting progress as appropriate; & resolving or escalating issues in a timely manner. • Supervises 1-3 research teams (app. 8-12 direct reports) on a day-to-day basis. • Organize, plan, and control workflow of the staff within the assigned teams and is responsible for ensuring clinical trials are conducted in compliance with federal, state and institutional guidelines	• Successful completion of a full 4-year course of study in an accredited college or university a major such as social or health science or related; OR appropriate combination of education and experience and 5 years' research study or other relevant experience required; OR • Successful completion of a full course of study in an accredited college or university leading to a master's or higher degree in a major such as social or health science or related; OR combination of education and experience and 3 years' research study or other relevant experience. • Supervisory or project management experience required. • Clinical Research Coordinator Certification. If not currently obtained, will be required within 9 months of hire.	No	

Duke Cancer Institute Job Responsibilities & Qualifications

Title of Position (e.g. study coordinator, research nurse vs. non-nurse, regulatory, pre-award finance, post-award finance, data analyst, manager, etc.)	**Main Responsibilities** (highlight 2 or 3 responsibilities of the role)	**Pre-requisites for Hiring** (e.g., degree, prior work experience, medical terminology, prior oncology experience, etc.)	**Career Ladder** (Yes or No)	**Comments**
Clinical Research Specialist	Assist with screening and specimen collection; Data submission	Associates Degree	Clinical Research Specialist, Sr is usually the next step, but different job classification	
Clinical Research Specialist, Sr	Screening, consent and documentation for non-complex studies; Specimen collection; data submission	Associates Degree + 1 year experience	Clinical Research Coordinator is usually the next step, but different job classification	
Clinical Research Coordinator	Screen, consent and documentation for complex studies; Assists with monitoring visits/audit preparation and response; May be responsible for specimen collection and data submission	Associates Degree + 2 years of experience OR Bachelor's Degree	**Yes** – Tiered 1 - 3	
Clinical Research Coordinator, Sr	Conducts and provides oversight to the study team for screening, consenting, documentation, specimen submission and data collection; Leads monitoring visits/audit preparation and response	Associated Degree + 6 years of experience OR Bachelor's Degree + 4 years of experience	Research Program Leader or Assistant Research Practice Manager is usually the next step, but different job classification	
Clinical Research Nurse Coordinator	Screen, consent and documentation for complex studies; Assists with monitoring visits/audit preparation and response; May be responsible for specimen collection and data submission; RN responsibilities	RN + 1 year of clinical experience	**Yes** – Tiered 1- 3	
Clinical Research Nurse Coordinator, Sr	Conducts and provides oversight to the study team for screening, consenting, documentation, specimen submission and data collection; Leads monitoring visits/audit preparation and response; RN responsibilities	RN + 1 year of clinical experience + 4 years of research experience	Research Program Leader or Assistant Research Practice Manager is usually the next step, but different job classification	
Regulatory Coordinator	IRB, FDA and Research Data Security Plan submissions; Maintenance of	Associates Degree + 2 years of experience OR Bachelor's Degree	**Yes** – Tiered 1 - 3	

Duke Cancer Institute Job Responsibilities & Qualifications

	regulatory binders; Assists with monitoring visits/audit preparation and response; Assist with protocol feasibility			
Regulatory Coordinator, Sr	Conducts and provides oversight to the study team for IRB, FDA and Research Data Security Plan submission, maintenance of regulatory binders; Leads monitoring visits/audit preparation and response; Assists with feasibility	Associated Degree + 6 years of experience OR Bachelor's Degree + 4 years of experience	Research Program Leader or Assistant Research Practice Manager is usually the next step, but different job classification	
Research Program Leader	Program, Project, and Portfolio Management; Assist with development and editing research proposals, protocols, and manuscripts; Selects and implements data capture methods	Bachelor's Degree + 4 years of research experience OR Master's degree + 2 years of research experience	**Yes** – Tiered 1- 2	
Research Program Leader, Sr	Program Management and Project Development; Leads the development and editing research proposals, protocols, and manuscripts; Represents the research program; Provides oversight to study staff	Bachelor's Degree + 8 years of research experience OR Master's degree + 6 years of research experience	No	
Assistant Research Practice Manager	Supervise and provide guidance on research operations and finances for the studies within the assigned division; Hiring and staff oversight of division; Develops procedures, policies and training;	Bachelor's Degree + 6 years of research experience OR Master's degree + 2 years of research experience	Research Practice Manager is usually the next step, but different job classification	
Research Practice Manager	Oversee the operations and finances of studies; Manage staff effort; Serve as an expert research for study conduct; Leads process development and staff training	Bachelor's Degree + 8 years of research experience OR Master's degree + 6 years of research experience	No	

Stanford Cancer Center Job Responsibilities & Qualifications

Title of Position (e.g. study coordinator, research nurse vs. non-nurse, regulatory, pre-award finance, post-award finance, data analyst, manager, etc.)	**Main Responsibilities** (highlight 2 or 3 responsibilities of the role)	**Pre-requisites for Hiring** (e.g., degree, prior work experience, medical terminology, prior oncology experience, etc.)	**Career Ladder** (Yes or No)	**Comments**
Assistant Clinical Research Coordinator ACRC	Assist with kits, reimbursement tracking, support staff	Two-year college degree, prior experience, general knowledge medical terminology	Yes – see roles CRC track	
Clinical Research Coordinator Associate CRCA	Data entry, back-up to coordinator, financial tracking	Two-year college degree, with two years' experience, or a bachelor's degree, no experience, Medical terminology	Yes – See roles CRC track	
Clinical Research Coordinator 2 CRC2	Consenting, sponsor interactions, patient management on trial	Bachelor's degree, two years' experience or combination of education and experience	Yes – see roles CRC track	
Lead Clinical Research Coordinator	Back-up to Manager, training staff, quality oversight	Bachelor's degree, two years' experience or combination of education and experience – leadership qualities	Yes – see roles CRC track	
Project Specialist	Specializing in study start-up, quality oversight, financial management	Bachelor's degree, two years' experience or combination of education and experience	Yes- see roles CRC track	
Clinical Research Manager	Manage team of CRCs in above roles, management of disease group portfolio, oversight of quality, operations disease group specific	Bachelor's degree, two years' experience or combination of education and experience. Previous management experience, or performance in a lead role		
RN 1	Support patient screening and enrollment, triage adverse events, answer clinical questions	Bachelor's degree in Nursing, two-years' experience		
RN 2	Support patient screening and enrollment based on expertise, oversee adverse event documentation, resolutions, support more complex clinical trials by answering clinical questions	Bachelor's degree in Nursing, five-years' experience		
Regulatory	Support and manage regulatory submissions, regulatory oversight			
Finance	Budget development, contract support and labor management			
Oncore Data Analyst	OnCore protocol management, development, and reports			
Quality	Manage quality oversight, internal quality audits available for review of questions			

Huntsman Cancer Center Job Responsibilities & Qualifications

Title of Position (e.g. study coordinator, research nurse vs. non-nurse, regulatory, pre-award finance, post-award finance, data analyst, manager, etc.)	**Main Responsibilities** (highlight 2 or 3 responsibilities of the role)	**Pre-requisites for Hiring** (e.g., degree, prior work experience, medical terminology, prior oncology experience, etc.)	**Career Ladder** (Yes or No)	**Comments**
Study Coordinator	Entry-level data, long-term follow-up	Degree	Yes	Most frequently promoted into either CRC or RDC roles after experience
Research Data Coordinator	Data entry/query resolution, facilitate monitor visits	Degree, prefer research or healthcare experience	Yes	Can be a senior RDC; some move to CRC
Clinical Research Coordinator	Consent, scheduling, and documenting procedures	Degree, requires research experience	Yes	Can be a senior CRC
Clinical Research Nurse	Consent, scheduling, and documenting procedures; additional duties requiring licensure	Nurse licensure	No	Not currently a career ladder
Project Administrator	Training and mentorship, quality oversight	Oncology coordinating experience	No	In coordination teams, lab team, satellite sites, etc.
Program Manager	Personnel management, portfolio management	Research experience, certification (SOCRA or ACRP) preferred	No	
Pre-award Finance	MCA, budget negotiations		No	
Post-award Finance	Billing, invoicing, etc.		No	
Lab Specialist	Specimen procurement, processing, and shipment; ECGs/Holters		Yes	Can be senior or move into PA role
Regulatory Coordinator	Regulatory study management	Degree	Yes	Can be a senior; divided into start-up and maintenace
NCI and Affiliate Program Manager	Manage affiliates, oversight of NCI-sponsored studies	Degree, research experience	No	
Training and Mentorship Program Manager	Training and onboarding of new staff, investigator training	Degree, research experience	No	
Data Systems Analyst	CTMS and other software administration, data reporting	Degree and experience	No	

Wilmot Cancer Institute Job Responsibilities & Qualifications

Title of Position (e.g. study coordinator, research nurse vs. non-nurse, regulatory, pre-award finance, post-award finance, data analyst, manager, etc.)	**Main Responsibilities** (highlight 2 or 3 responsibilities of the role)	**Pre-requisites for Hiring** (e.g., degree, prior work experience, medical terminology, prior oncology experience, etc.)	**Career Ladder** (Yes or No)	**Comments**
Data Manager	Data entry	High school diploma	No	
Study Coordinator I (non-nurse)	Entry level SC. Simple protocol coordination	Bachelor's degree plus 1 year experience	No	
Study Coordinator (non-nurse) II	Competent SC. Manages reasonable work load and moderate complexity.	Bachelor's degree and 2 years' experience	No	
Study Coordinator III	Veteran. Complex protocols with some training of new staff responsibilities.	Bachelor's degree and 3 years' experience. CCRP/ACRP	No	
Clinical Trials Manager	Supervise SC and DM staff on team. Hiring, performance assessment, manage work allocation/assignment. QA teams work.	Bachelor's degree and 5 years' experience. CCRP/ACRP	No	
Research Nurse	Patient facing. Physician and patient research resource/support in clinic.	RN	No	
Research Nurse Manager	Supervise Research Nurses. Hiring, performance assessment, manage work allocation/assignment. QA teams work.	RN with research experience and demonstrated leadership abilities.	No	
Regulatory Start-up	Pipeline protocols until open to accrual	Bachelor's degree	No	
Regulatory maintenance	Regulatory support of disease team protocols opens to accrual	Bachelor's degree	No	
Regulatory Manager	Supervise Regulatory staff. Hiring, performance assessment, manage work allocation/assignment. QA teams work.	Bachelor's degree and 5 years' experience. Regulatory or research certification	No	

WILMOT CANCER INSTITUTE PROPOSED CAREER LADDER

Title	Category	Recommended Salary	*National Average	Related Experience	**Qualification
Clinical Research Coordinator Track					
HSRC I Study Coordinator I	**Novice:** Entry level	Grade 51 $40-50	$50,800	1 year	Bachelor's or Associates Degree
HSRC II Study Coordinator II	**Competent:** Mid-level	Grade 53 $50-65	$58,700	2 years	Bachelor's Degree
Sr HSRC Study Coordinator III	**Veteran:** Experienced	Grade 55 $55-70	$64,600	3 years	Bachelor's Degree CCRP/ACRP
Administrator II Clinical Trials Manager (CTM)	**Supervisor:** Experienced	? Grade $60-80	$80,000	5 years	Bachelor's Degree Master's Degree preferred CCRP/ACRP
Data Entry Track					
Student position	**TBD**	$15-18/hr		0 years	
Data Entry Tech I	**Entry level:** Simple data entry tasks as assigned	? Grade $35-45	$47,400	0 years	High School Diploma
Data Entry Tech II	**Competent:** Experienced DET More complex DET and ability to take initiative and organize/prioritize several projects	Grade 51 $40-50	$55,100	1 year	High School Diploma
CTO Data Manager	**Veteran:** Training staff. SME in DM and data reporting Oversee all CTO data	Grade 55 $55-70	$63,500	3 years	Bachelor's Degree

2/12/2021hp

UNIVERSITY OF MIAMI IMPLEMENTED CAREER LADDER

Title	Category	Work Experience Requirement	Degree Requirement	Certification Requirement
Clinical Research Data Specialist (CRDS)	**Entry level:** Oncology only	0 years	High School Diploma	Not required
Clinical Research Associate (CRA)	**Entry level:** Non-oncology only	0 years	Associate's Degree	Not required
Clinical Research Coordinator 1 (CRC 1)	**Novice:** Entry level clinical research professional	1 year (in clinical research or relevant work experience)	Bachelor's Degree	Not required
Clinical Research Coordinator 2 (CRC 2)	**Competent:** Mid-level clinical research professional	2 years (in clinical research or relevant work experience)	Bachelor's Degree	Not required
Clinical Research Coordinator 3 (CRC 3)	**Veteran:** Experienced clinical research professional	4 years (in clinical research or relevant work experience)	Bachelor's Degree and certification for 6 months or longer	Current Research Coordinator certification by the Association of Clinical Research Professionals or Society of Clinical Research Associates
Clinical Research Manager	Fully functional, seasoned research coordinator	5 years (as clinical research coordinator)	Master's Degree	Current Research Coordinator certification by the Association of Clinical Research Professionals or Society of Clinical Research Associates

Feb 2020

Part 2: General Onboard Training for CTO

Title of Position	**General Training Required** (e.g., What do all new staff need to know?)	**How long does general training last?** (hours/days/weeks)	**Do you have a dedicated educator role?** (Yes/No)	**If yes, what is their title?**	**If no, who provides training?**	**What training is offered?** (e.g., classes/ courses, certification, etc.)	**Comments**
General Onboarding to **Jefferson SKCC** CTO	We have an administrative section in our new employee binder with information about the office/hospital campus, ETO policy, dress code, phone greeting & email signature requirements, etc. Then we have competency trainings added into the binder as listed below… Depending on the persons role in our office, they may not need to complete each of the trainings but the majority of them apply to all staff. • Competency 1 - Ethical, Legal and Scientific Standards • Competency 2 - Oncology Basics • Competency 3 - Study Sponsors, Protocol Design and Feasibility • Competency 4 - Essential Documents • Competency 5 - Study Start Up • Competency 6 - Informed Consent	Training occurs over the 90 day probation period but most of the training occurs in the 1st month	Yes, we will starting June 1, 2021	Clinical Research Educator	Prior to the Educator position, the disease site team project managers, office directors and regulatory supervisors provided the training	Our hospital offers general research training every 6 months in addition to our office onboarding program. We also allow staff to participate in conferences for educational purposes as long as it fits into the budget.	

	• Competency 7 - Study Activities and Conduct • Competency 8 - Data Management • Competency 9 - Financial Components of Clinical Trials • Competency 10 - Laboratory and Pathology • Competency 11 - Test Article Accountability • Competency 12 - Subject Safety • Competency 13 - Response Criterion in Oncology Clinical Trials • Competency 14 - Quality Assurance • Competency 15 - IRB and Protocol Support Unit						

Title of Position	**General Training Required** (e.g., What do all new staff need to know?)	**How long does general training last?** (hours/days/weeks)	**Do you have a dedicated educator role?** (Yes/No)	**If yes, what is their title?**	**If no, who provides training?**	**What training is offered?** (e.g., classes/ courses, certification, etc.)	**Comments**
General Onboarding to **Vanderbilt Ingram Cancer Center** CTO	All staff required to attend CTO Integrated Orientation. Orientation covers an overview of the organization, introduction to research, and CTO-specific processes.	6 hours per day for 5 days	Yes	Clinical Research Educator		- Overview of VUMC, VICC, CTO - Basics of Research - Clinical Trials Process (opening a study -> IRB closure) - Clinical Investigation Team (sponsors, CROs, IRB, FDA, etc) - GCP - Professionalism - Intro to Protocols - Oncology 101 - HIPAA - Disease Assessment - Deviations - Eligibility - Cancer Therapies - AEs/SAEs - Informed Consent - Con Meds	

Title of Position	**General Training Required** (e.g., What do all new staff need to know?)	**How long does general training last?** (hours/days/weeks)	**Do you have a dedicated educator role?** (Yes/No)	**If yes, what is their title?**	**If no, who provides training?**	**What training is offered?** (e.g., classes/ courses, certification, etc.)	**Comments**
General Onboarding to **Dartmouth - Hitchcock Norris Cotton Cancer Center** CTO	CITI training on Human Subjects Protections, GCP, and Responsible Conduct of Research, then orientation at the institution level. This is followed by hands-on training for the specific role, in our department.	General training is approx. 2 weeks.	Yes, but it is not cancer-center specific and not fully rolled out (she's on maternity leave)	Manager Research Education and Professional Development	Training also provided by departmental leadership and senior level staff	Modules and certification via CITI, institution-developed courses for institutional orientation, and hands-on training at department level with work instructions/SOPs.	

Title of Position	**General Training Required** (e.g., What do all new staff need to know?)	**How long does general training last?** (hours/days/weeks)	**Do you have a dedicated educator role?** (Yes/No)	**If yes, what is their title?**	**If no, who provides training?**	**What training is offered?** (e.g., classes/ courses, certification, etc.)	**Comments**
General Onboarding to **Huntsman Cancer Institute** CTO	CITI HSP, GCP, good documentation practices, HIPAA, overview of the research program and institution, BBP; all administered in an online learning management system	4 weeks (intermixed with other activities)	Yes	Training and Mentorship Manager		35 "in-person" classes for coordination/leadership roles. 5-7 classes for other roles in Finance, lab, etc. whose teams oversee the majority of their training.	"See one, do one" is the model for mentoring which is handled on the individual team level.

Title of Position	**General Training Required** (e.g., What do all new staff need to know?)	**How long does general training last?** (hours/days/weeks)	**Do you have a dedicated educator role?** (Yes/No)	**If yes, what is their title?**	**If no, who provides training?**	**What training is offered?** (e.g., classes/ courses, certification, etc.)	**Comments**
General Onboarding to **MD Anderson Cancer Center** CTO	Human Subjects Protection Training (HSPT) GCP Clinical Research Training (CRT)- for certain titles Bi monthly - Continuing Education sessions (schedule altered due to covid) Additional Items: All Employees attend New Employee Orientation provided by HR. Nurses attend Nursing Orientation Simulation Center provides CPR Training for clinical staff- which includes all our RNs. However, for new employees, this is necessary prior to Hire. Some areas may require advanced life support training provided by Sim center. Research Biospecimen Training Policy (4 online modules) EEE/Sexual Misconduct- all employees yearly Research Nurse Residency Laboratory Draws EKG	HSPT- four hours total online. GCP- one hour online CRT- Ranges from one full day to three full day (RN and study coordinators involved in high risk treatment studies).	Our Central office Education group does have educator role.	Clinical Research Quality Specialist (Dept decided to have uniform titles to make it easier for HR purposes a few years ago. Prior to this our central office had a title- Research Educator).		HSPT is offered through learner paced online modules. CRT- Clinical Research Training is offered in a classroom environment- currently via Zoom. Continuing Education Sessions are currently done via Zoom. Typically Auditorium. Nursing Orientation is a combination of online and classroom courses. Some activities are hands on. Same for all other trainings- some are online modules. Some are classroom courses which are probably going to remain partially Zoom and partially in the classroom moving forward.	

	Epic Training Routine checkoffs for some nurses- conducted by Division of Nursing/ others if they are super users Certification Recommended for experienced: OCN- provided by ONS SOCRA- CCRP ACRP- CCRC, CCRA						

Title of Position	**General Training Required** (e.g., What do all new staff need to know?)	**How long does general training last?** (hours/days/weeks)	**Do you have a dedicated educator role?** (Yes/No)	**If yes, what is their title?**	**If no, who provides training?**	**What training is offered?** (e.g., classes/ courses, certification, etc.)	**Comments**
General Onboarding to **Wilmot Cancer Institute** CTO	Overview of CTO and Mission General understanding of all CTO roles Research "101" Oncology "101" SOPs Specific resources Shadowing experiences All systems: e-reg/CTMS General geography and lay out of site Buddy system	Weeks/months depending on prior experience	Yes	Clinical Research Training and Development Coordinator	Training is conducted in partnership with the disease group Clinical Trial Manager	Classes SOP training Shadowing Role specific certification: e.g phlebotomy/tech associates Research certification encouraged and reimbursed CITI OHSP courses as applicable	We are currently developing: • Competency testing • Research Nurse curriculum • Manager curriculum

Title of Position	**General Training Required** (e.g., What do all new staff need to know?)	**How long does general training last?** (hours/days/weeks)	**Do you have a dedicated educator role?** (Yes/No)	**If yes, what is their title?**	**If no, who provides training?**	**What training is offered?** (e.g., classes/ courses, certification, etc.)	**Comments**
General Onboarding to **Robert H. Lurie Comprehensive Cancer Center** CTO	Introduction to the Cancer Center, Research 101 (drug development process, ICH GCP guidelines, FDA CFR and HIPAA), Departmental Templates and their uses, Staff Responsibilities (regarding patient visits, administrative tasks, etc), EPIC training, Adverse Events/Concomitant Medication Training, Audits & Inspections Training, Oncology 101 Training (led by clinical research nurses, content includes solid tumor, hematologic malignancies, genetic mutations & "personalized medicine", frequently seen AE's in Oncology, etc.)	~4-6 weeks, including 7+ hours of mandatory direct training sessions	Yes, training is a collaboration between the manager and the educator throughout the onboarding process.	Project Manager		Department: in-person/remote training sessions, Data Management online training course, 1:1 topic specific training available if needed University: NUCATS CRC Basic Training, CReWE Monthly "brown bag" sessions, AACR monthly meetings	We have training checklists that are signed off by managers with new staff. Weekly check ins first month, month 3 and month 6 follow up to re-review concepts there are questions on.

Title of Position	**General Training Required** (e.g., What do all new staff need to know?)	**How long does general training last?** (hours/days/weeks)	**Do you have a dedicated educator role?** (Yes/No)	**If yes, what is their title?**	**If no, who provides training?**	**What training is offered?** (e.g., classes/ courses, certification, etc.)	**Comments**
General Onboarding to **Duke Cancer Institute** CTO	Human Subject Protection (HSP) and Good Clinical Practice (GCP); General HR Training (HIPAA, Fire/Life Safety, Compliance, Diversity & Inclusion); General Clinical Research Training (informed consent & recruitment, IRB submissions and reporting, Responsible Conduct of Research(RCR)); System Training (electronic IRB (iRIS), CTMS (OnCore), EMR (Epic), electronic regulatory binder (eReg))	90 days probationary/trial period, with the intent that all/most online training modules are completed within the first 30 days	Yes, the position is involved in developing training program. They do NOT directly train new employees.	Education & Training Coordinator	Training is a team effort and includes the direct supervisor, disease group team members and member(s) of other disease groups with like titles.	HSP, GCP, and RCR through CITIProgram; Other training modules are via the Duke Learning Management System (LMS) and the Duke Occupational & Environmental Safety Office.	The Duke Office of Clinical Research (DOCR) is responsible for developing the training modules available for clinical research in general at Duke. The Duke Cancer Institute's Education & Training Coordinator has helped developed a comprehensive training plan (checklist) for general onboarding. We are currently working on supplementing this general onboarding plan with role specific training plans for Clinical Research Nurses, Clinical Research Coordinators, Data Coordinators and Regulatory Coordinators. We intend to make benchmarks for 30, 60, 90 days and 6 months to start.

Title of Position	**General Training Required** (e.g., What do all new staff need to know?)	**How long does general training last?** (hours/days/weeks)	**Do you have a dedicated educator role?** (Yes/No)	**If yes, what is their title?**	**If no, who provides training?**	**What training is offered?** (e.g., classes/ courses, certification, etc.)	**Comments**
General Onboarding to **Wake Forest Baptist Comprehensive Cancer Center** CTO	CITI Certifications: Biomedical & GCP Internal Clinical Research Study Staff Orientation (14 training modules which evaluate key knowledge for implementing human research protocols in accordance with regulatory guidelines and institutional policies)	4-6 weeks	Yes	Clinical Research Educator		Classes/courses, certifications, New staff assigned to Preceptor to complete training	

Title of Position	**General Training Required** (e.g., What do all new staff need to know?)	**How long does general training last?** (hours/days/weeks)	**Do you have a dedicated educator role?** (Yes/No)	**If yes, what is their title?**	**If no, who provides training?**	**What training is offered?** (e.g., classes/ courses, certification, etc.)	**Comments**
General Onboarding to **UAMS Winthrop P Rockefeller Cancer Institute** CTO	Everything: Policies, SOPs, EPIC training, clinical trial management suite, required trainings: (IATA, Part 11, etc), new employee checklists, human subject protections, cooperative group trainings	We don't put anyone on their own for at least 6 weeks, but training continues throughout. It depends on experience and background on how long training will last. I firmly believe a solid year is needed for someone new to oncology research for them to be fully operational.	No, but have one planned/needed.		We provide a mentor assignment as well as partner them with other staff. We encourage them to spend a couple of weeks with each person before starting out on their own.	We have a local certified research specialist training that is helpful but provides overviews.	More formal training is needed. Most of our training is done by peer to peer or on the job training.

Title of Position	**General Training Required** (e.g., What do all new staff need to know?)	**How long does general training last?** (hours/days/weeks)	**Do you have a dedicated educator role?** (Yes/No)	**If yes, what is their title?**	**If no, who provides training?**	**What training is offered?** (e.g., classes/ courses, certification, etc.)
General Onboarding to **Stanford** CTO	All clinical research staff must complete the seven session orientation. New staff must complete all sessions during their first 6 months. All sessions are open to staff, fellows, and investigators involved in clinical research at SCI. Specific sessions may serve as a refresher for existing research staff, or may be appropriate for CRAs and others based upon responsibilities.	Over six months and can be repeated	No		Managers/Lead Coordinators	Classes/certifications

Attachment 2 - Training and Classes Offered at Each Participating Cancer Center

Title of Position	What systems are new hires being trained into?	What classes/courses are offered for general cancer center onboarding?	What classes/courses are offered for CTO onboarding?	How often do you offer refresher classes/courses?
General Onboarding to: Vanderbilt Ingram Cancer Center, Clinical Trials Office	Oncore Florence Epic	Essentials of Systemic Therapies for the Oncology Nurse 1. State the principles guiding cancer, chemotherapy, biotherapy, and targeted therapy (standard regimens and clinical trials) and response based upon a basic understanding of cancer cell features and behavior. 2. Discuss how systemic treatments for cancer (chemotherapy, hormone therapy, molecular targeted therapy, and immunotherapy) work, including principles guiding cancer therapy and effects on cell proliferation. 3. Describe classifications and associated side effects of chemotherapy, molecular targeted therapy, and immunotherapy. 4. Articulate nursing standards and available resources that address nursing practice for safe administration of chemotherapy, biotherapy, and targeted therapy, including patient education. 5. Describe the critical safety process in preparation, administration and post administration of chemotherapy, biotherapy, and targeted therapy, including dose calculation, routes of administration and safe handling precautions for	Overview of VUMC, VICC, CTO with Organization Chart Basics of Clinical Research Clinical Trials Process (opening a study -> IRB closure) Clinical Investigation Team (sponsors, CROs, IRB, FDA, etc.) GCP Professionalism & Escalation Pathways-Culture of Quality Intro to Protocols Intro to Oncology HIPAA SRC/Disease Team Structure Deviations Eligibility Adverse Events Serious Adverse Events Informed Consent	Orientation is held monthly and is used as a resource for refresher classes/courses.

		the nurse and patient while managing hazardous drugs. 6. Describe two immediate complications that can occur during the administration of chemotherapy, biotherapy, and targeted therapy, including risk factors and management of each. 7. Identify critical assessment parameters and nursing interventions for chemotherapy, biotherapy, and targeted therapy related myelosuppression. 8. Describe incidence, risk factors, assessment, and interventions for management of chemotherapy, biotherapy, and targeted therapy induced nausea and vomiting. 9. Discuss potential sexual and reproductive concerns for patients who receive chemotherapy, biotherapy, and targeted therapy including assessment and communication and management strategies. 10. Discuss ethical and legal issues that nurses may face when administering chemotherapy, biotherapy, and targeted therapy, incorporating standards, laws, and position statements as guides. 11. Apply evidence-based nursing interventions to prevent, minimize and manage symptoms associated with the following exemplar regimens: a. Breast Cancer: AC T&H	Con Meds Cancer Health Disparities/Broadening Participation Data Management Coordinating Center and IIT Development Coverage Analysis and Billing Compliance IDS Clinical Trials Processing Core Intro to Treatments CAR T Disease Assessment Workflows Regulatory Reporting Requirements OnCore: Introduction to the System Florence Training OnCore Exercise	

		i. Cardiomyopathy ii. Hemorrhagic cystitis iii. Peripheral Neuropathy iv. Alopecia b. Multiple Myeloma: Bortezomib, Lenolidamide, Dexamethasone, and Melphalan i. Oral adherence ii. Constipation iii. Oral Mucositis iv. Hepatotoxicities c. Non-Hodgkin's Lymphoma Regimen: DHAP + R i. Ocular toxicities ii. Ototoxicities iii. Cerebellar toxicities iv. Cognitive impairment v. Nephrotoxicities d. Lung Cancer: Nivolumab i. Pulmonary Toxicities ii. Cutaneous Toxicities e. Colon Cancer: FOLFOX + Bevi i. Diarrhea ii. Weight loss and Cachexia 12. Fatigue Oncology Care Basics 13. Define basics cancer 14. Review hematopoiesis 15. Describe risk factors, diagnostic work up, treatment strategies, and nursing implications for the following:		

		a. Leukemia b. Lymphoma c. Multiple myeloma d. Lung cancer e. Pancreatic cancer f. Head and neck cancer g. Breast cancer 16. Examine prevention, screening, and treatment of oncologic emergencies through case study exemplars: a. Tumor lysis syndrome b. Superior vena cava syndrome c. Disseminated intravascular coagulation d. Spinal cord compression e. Hypercalcemia 17. Discuss nursing interventions and patient education strategies for symptom management: a. Fatigue b. Myelosuppression c. Neutropenic fever/sepsis d. Neuro-cognitive side effects e. Gastrointestinal side effects f. Skin, hair, and nail side effects		

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General Onboarding to: UPMC Hillman Cancer	Internal CTMS system (CTMA) ARIA Epic PowerChart Currently onboarding REDCap/Oncore and E-reg	*New Beginnings* – a specific overview about the Hillman Cancer Center *Foundations To Practice In Oncology Courses* – These are 5 independent courses that include: Treatment Overview, Solid Tumor Overview, Symptom Management Overview, Hematological Emergencies, and Hematological Malignancies Overview *Comprehensive Chemotherapy and Biological Therapies course* – This is a 4-day course that reviews treatment agents. Upon successful completion of the post course exam, staff can proceed to chemo skills validation. All research nurses take the course even though they do not administer therapy themselves.	All new CRS staff attend a thirteen-day orientation period with the CRS QA team to learn basic research principles prior to training with a mentor in an assigned disease center. Each day of the thirteen-day orientation period includes one-on-one training regarding specific components of the research process. Companion *Skills Labs,* formatted as either a quiz or are a task-based exercise, are completed by the new hires for the topics reviewed with the QA team. The research training includes everything from an overview of research to reading/navigating protocols, consenting, the use of the EMR, completing and using source documents, to the workflows for a subject's treatment visit. Once the initial thirteen-day orientation is completed, the new staff train directly with a mentor in the assigned disease center. Biweekly *Touch Base* meetings are held once the ten-week mentorship begins to review experiences and set goals for the next two weeks of training. The Touch Base meetings continue until the disease center manager and QA manager sign off that the new hire has successfully completed the mentorship.	Staff can retake a lecture on an as needed basis, as identified by QA or management. The QA team is currently working on implementing an "open office hours" and refresher course schedule.

Attachment 2 - Training and Classes Offered at Each Participating Cancer Center

Title of Position	What systems are new hires being trained into?	What classes/courses are offered for general cancer center onboarding?	What classes/courses are offered for CTO onboarding?	How often do you offer refresher classes/courses?
General Onboarding to: Huntsman Cancer Institute	LMS: Canvas/Bridge EMR: Epic CTMS: OnCore SOPs: MasterControl	• HR onboarding discussing NCI designation and history of the cancer center • Introduction to Clinical Trials • Clinical Trials Life Cycle • Protocols 101	• Compilation of Source Documents • Research Documentation in the EMR • CTMS training • NCI-sponsored trials training • Data Training (basic and advanced) • Conmeds/medical history • Adverse Events • Serious Adverse Events • Monitor Visits • Informed Consent • Investigational Pharmacy • Deviation Reporting • Laboratory Basics • Tips and Tricks • Phase 1 Clinical Trials • Audits • Prescreening	New hires start on the 1st and 16th of each month; the courses start with new hires and all employees are welcome to attend. The courses are recorded and available in Canvas for refreshers.

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Title of Position	What systems are new hires being trained into?	What classes/courses are offered for general cancer center onboarding?	What classes/courses are offered for CTO onboarding?	How often do you offer refresher classes/courses?
General Onboarding to: Robert H. Lurie Comprehensive Cancer Center of Northwestern University	• Home grown CTMS system called (NOTIS) • Internal study activation system called Launchtrack • NU eIRB+ System • Complion eReg • CTSU • NCI CIRB • Advarra/WCG/Other external IRBs (for Reg staff) • EPIC • NU CTMS system/billing called Study Tracker	• CITI Training/GCP Training • NU HR training/overview • Northwestern Medicine Training for Nurses • Clinical Research Workforce Excellence training (must attend 1 instructor led workshop per year) • Conflict of Interest Training • Unconscious Bias Training	• Intro to the Cancer Center • Research 101 • Oncology 101 • "How To"-general info about hospital clinics • Coursera.org modules • Review of SOPs and Job aids • Adverse Event Training • Audits and Inspections • Study Start-UP • QA team overview • CTO templates • EPIC training • Frequent Contacts • Regulatory 101 Training	• Clinical, Reg and QA courses offered monthly • Intro to Clinical Research offered 3 times a year that anyone can attend.

Attachment 2 - Training and Classes Offered at Each Participating Cancer Center

Title of Position	What systems are new hires being trained into?	What classes/courses are offered for general cancer center onboarding?	What classes/courses are offered for CTO onboarding?	How often do you offer refresher classes/courses?
General Onboarding to: Indiana University Melvin and Bren Simon Comprehensive Cancer Center	CTMS (OnCore), EMR (Cerner and EPIC), eConsent (ClinOne), REDCap, SharePoint, MS Teams, Canvas	Clinical Research Staff Education workshops to focus on GCP topics starting pre-12 weeks, at 6-24 months, and 3+ years; EMR training	We have 44 topic-specific lessons in our orientation that cover every aspect of trial management from activation to closeout, HIPAA compliance, role-specific responsibilities, etc.	We do a monthly Education Series where we focused on new processes and procedures. Pre-COVID we also had a monthly Refresher series to review policies and procedures that are already in place. These were put on hold during COVID and remain on hold. The campus Clinical Research Center also provides monthly educational series.

Title of Position	What systems are new hires being trained into?	What classes/courses are offered for general cancer center onboarding?	What classes/courses are offered for CTO onboarding?	How often do you offer refresher classes/courses?
General Onboarding to: Stanford Cancer Clinical Trials Office	OnCore CTMS Epic HER Stanford systems (IRB) CITI	Hospital systems/working with clinics and units	Clinical training in addition to general Stanford training • Overview of Clinical Research at the Stanford Cancer Institute • A Day in the Life of a Clinical Research Coordinator • OnCore Basic Training • Introduction to Informed Consent Safety Documentation and Reporting • Study Financial Management. • Coverage analysis • Study Start Up and Regulatory Documentation	All class are offered to be repeated at any time.

Attachment 2 - Training and Classes Offered at Each Participating Cancer Center

Title of Position	What systems are new hires being trained into?	What classes/courses are offered for general cancer center onboarding?	What classes/courses are offered for CTO onboarding?	How often do you offer refresher classes/courses?
General Onboarding to: Winship Cancer Institute, Emory University	• Complion • OnCore • Local IRB (Emory) eIRB system • CTSU • CIRB IRB Manager • WCG IRB Connexus • Advarra IRB • ERMS • Powerchart • Compass (financials)	• Emory offers classes via their Emory Learning Management System (e.g., CRC 2-day introduction to clinical research at Emory, etc.) • Emory IRB training available via their website (e.g., webinars & previous recordings are available for viewing) • CITI training for Biomedical Focus, GCP and ICH, and HIPAA	• CTO Orientation Training offered to new staff monthly • Regulatory training (e.g., study start-up vs maintenance)	• Regulatory training done bi-weekly done by AD, Regulatory (mostly for new staff) • Sr. Regulatory Specialist: weekly training for new staff (e.g., various materials are presented) • Recording our training sessions

Title of Position	What systems are new hires being trained into?	What classes/courses are offered for general cancer center onboarding?	What classes/courses are offered for CTO onboarding?	How often do you offer refresher classes/courses?
General Onboarding to: Norris Cotton Cancer Center	OnCore, Epic (for clinical staff), eReg and Click IRB (for regulatory staff), RAVE	Institutional orientation (normally in person, currently suspended due to pandemic)	CITI Biomedical Research, CITI Good Clinical Practice, CITI Responsible Conduct of Research	CITI refreshers are required every three years but can be repeated on demand as needed.

Attachment 2 - Training and Classes Offered at Each Participating Cancer Center

Title of Position	What systems are new hires being trained into?	What classes/courses are offered for general cancer center onboarding?	What classes/courses are offered for CTO onboarding?	How often do you offer refresher classes/courses?
General Onboarding to: Wilmot Cancer Institute: Specifically for the position of Clinical Research Training and Development Coordinator Position	All are role dependent: These are the 3 main ones: more are offered dependent on specific role: Embark OnCore (CTMS system) RedCap EPIC eRecord Complion (eRegulatory)	Depends on role, depends on classes Nursing is most intensive We incorporate general cancer training into our CTO training	GCP Study conduct Role of Regulatory and Finance Protecting PHI AE reporting Clinical Trials history Biology of Cancer: self-learning through Coursera Other training is role specific	No set timeline at this time. Working on a competency program of sorts. Additional training offered as need arises