May 2019

Regulatory Coordinator Readiness Tool

Duke University

Clinical Research Professionals Working Group ● Regulatory Coordinator Readiness Too

Use this tool to plan for tier advancement/ setting for most tiered clinical research job classifications at Duke (Clinical Research Coordinators, Clinical Research Nurse Coordinators, and Regulatory Coordinators). This is to be used by employees and their supervisors faculty, and HR managers to decide whether tier advancement/setting is appropriate. Note – this is a self-assessment tool. If tier advancement/setting appears to be appropriate, each employee will be evaluated using standardized assessments for the Core, Other, a Leadership competencies. Candidates for Tier 3 will also receive committee review of their application.

It is recommended that conversations about tier advancement/setting occur around the time of the annual performance evaluation, durir discussions about professional development. Tier advancement/setting is a separate process from performance management.

Tier 1	Tier 2	Tier 3
9-35 points	36-83 points	84+ points
	Minimum criteria	
Accumulate a total of 9 points	**Accumulate a total of 36 points**	**Accumulate a total of 84 points**
…usually by getting 1 point for reaching "fundamental" level in each of the 9 Core competencies. Swap out up to 3 Core competencies for Other competencies. AND Meets ALL Leadership competencies at the fundamental level.	…usually by getting 2 points for reaching "skilled" level in each of the 9 Core competencies, and getting 2 points for reaching skilled level in 9 more Other competencies. Swap out up to 3 Core competencies for Other competencies to allow for specialized skill sets. AND Meets ALL Leadership competencies at the skilled level.	**…**usually by getting 4 points for reaching "advanced" level in each of the 9 Core competencies, and getting 4 points for reachi advanced level in 12 more Other competencie Swap out up to 3 Core competencies for Othe competencies. May accumulate points by taki on Core or Other responsibilities in Senior role (no more than 3 Senior responsibilities). AND Meets ALL Leadership competencies at the advanced level. AND Submits portfolio for review. Committee revie application for advancement/setting.

Questions?

Questions on this process can be directed to your HR manager.

Regulatory Readiness Tool Name: _____

Core Competencies – Regulatory

	Competency	Assessment Method K	O	Q	R	C	Self-Assessment F	S	A	E	Notes
Research Operations	Study level documentation	X		X	X						
	Interactions and Submissions with IRB			X	X						
	Institutional Regulatory Documentation			X	X						
	Institutional Regulatory Policies and Processes	X									
	Monitoring & Audits				X						
Ethic & Safety	Adverse Event Reporting	X									
Site/Study	Study Closeout				X						
	Managing risk			X	X						
Data	Data Security & Provenance	X									TOTAL # self-assessed
							1	2	4	8	Points per competency
											Competency points (multiply columns above)
											Total points in CORE competencies

*** Assessment Method**

K = Knowledge Assessment
O = Direct Observation
Q = QA of Existing Records/Systems
R = Self + Manager Report
C = Case Studies

**** Self-Assessment of Level**

Although determination of level will be made via assessment during tier advancement/setting, you can estimate/self-assess your own current level.

F = Fundamental
Can perform the task and/or exhibit the knowledge at an essential or foundational level. May require some coaching or supervision.

S = Skilled
Can perform task or skill independently, consistently, accurately, and has a moderate level of expertise. Efficient and high quality work. Able to independently navigate resources and uses tools well.

A = Advanced
Demonstrates advanced skills and knowledge and the ability to teach, coach, or supervise others. Consistently applies critical thinking and problem solving.

E = Expert - Senior Classification
Provides oversight and high level expertise to multiple research teams in this skill/area. Designs and implements innovative processes in this area. May serve as an expert resource across Duke in this area.

Other Competencies – Regulatory

		Assessment Method					Self-Assessment				Notes
	Competency	K	O	Q	R	C	F	S	A	E	
Research Operations	Consent		X								
	Recruitment				X						
	Subject Management & Retention				X						
	Prepare for & Conduct Study Visits				X						
	Specimen Collection & Prep		X								
	Investigational Product	X				X					
	Screening				X						
	Electronic management of research participants	X	X			X					
	Subject level documentation			X	X						
	Contracts & Agreements					X					
											TOTAL # self-assessed
							1	2	4	8	Points per competency
											Competency points (multiply columns above)
											Subtotal 1 for Other Competencies

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Other Competencies – Regulatory

		Assessment Method					Self-Assessment				Notes
	Competency	K	O	Q	R	C	F	S	A	E	
Research Ops	Regulatory compliance – international studies				X						
	Interacting with the FDA				X						
	Technology management				X						
	Team meetings				X						
	Use and Development of SOPs			X	X						
Scientific Concepts	Protocol Development	X		X	X						
	Literature Review			X	X						
	Research Design	X									
	Scholarly Publishing				X						
	Proposal Development			X	X						
											TOTAL # self-assessed
							1	2	4	8	Points per competency
											Competency points (multiply columns above)
											Subtotal 2 for Other Competencies

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Other Competencies – Regulatory

	Competency	Assessment Method K	O	Q	R	C	Self-Assessment F	S	A	E	Notes
Site/Study	Determining Participation in Trials				X						
	Managing Resources				X						
	Operational Plans			X	X						
	Site Visits & Sponsor Training				X						
Ethics	Identify/document AEs	X									
Data/informatics	Data collection/entry				X						
	Data flow					X					
	Data Corrections, Queries, QA				X						
	Other _____	Provide self-report with manager attestation. Attach additional documentation as relevant. Only one is allowed. (Any other competency not listed that supports advancement/setting-may include 1 RPL competency)									
											TOTAL # self-assessed
							1	2	4	8	Points per competency
											Competency points (multiply columns above)
											Subtotal 3 for Other Competencies

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Leadership Competencies (see next page)

	Assessment Method					Self-Assessment*				Notes
Competency	K	O	Q	R	C	T1	T2	T3	Meet min?	
Continual Learning		X		X						
Organizational Agility				X						
Teamwork		X								
External Awareness & Contribution				X						
Subject Matter Expertise				X						
Resilience & Adaptability				X						
										Meet minimum for desired tier?

*** Assessment Method**

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**** Self-Assessment of Level**

Leadership competency levels are described on the next page. Find the box that best describes your current level in that competency and mark on this sheet.

Note that in order to move to the next tier, you must meet all of the leadership competencies for that tier. For example, if you are applying to move to Tier 2, you must meet all Tier 2 leadership competencies listed on the next page.

SCORING	
Total Points for Core Competencies	
Total Points for Other Competencies	
GRAND TOTAL POINTS (add 2 rows above)	
Meet minimums for leadership?	

Notes:

Tier Advancement/Setting Minimums

Tier 1	9 Points All T1 leadership
Tier 2	36 Points All T2 leadership
Tier 3	84 Points All T3 leadership Submission of portfolio

Leadership competencies by tier

	Tier 1	Tier 2	Tier 3
Continual Learning	Completes the required training as evidenced by the training record.	Recognizes opportunities for own growth, takes responsibility to increase skill or knowledge level.	Actively seeks opportunities to increase skill or knowledge level for self and shares opportunities with others involved in clinical research. Seeks feedback from others and uses other sources of information (e.g., professional organizations, publications) to identify appropriate areas for learning.
Teamwork	Provides the information, communication, cooperation, and support necessary for the study team/department/CRU to function effectively. Works with the team to solve problems as identified.	Provides the information, communication, cooperation, and support necessary for groups outside your study team/department/CRU. Considers "what if" scenarios in response to issues to help facilitate the best solution.	Provides direct supervision, mentors, or engages in performance support. Recognizes opportunities for improvement and creates and leads teams to meet those objectives.
Subject Matter Expertise	N/A	Provides documentation of instances of demonstrating expertise in clinical research or a therapeutic area within the study team, department, or CRU.	Provides documentation of instances of demonstrating expertise in clinical research or a therapeutic area outside of the study team, department, or CRU.
Resilience & Adaptability	Adapts smoothly and positively to organizational changes.	Assists others in adapting smoothly and positively to changes. Is able to cope well with demanding situations by using the resources available.	Copes well with demanding situations through problem recognition. Can successfully navigate difficult conversations and utilizes the available resources when needed. Is quick to embrace change when required. Assists others to embrace change.
External Awareness & Contribution	Attends key meetings and/or training.	Applies newly learned material back on the job.	Disseminates research updates to employees or faculty.
Organizational Agility	Has a basic understanding of which Duke organizational areas and individuals to contact to get things done.	Can independently work with Duke organizational areas and individuals to get things done. Individuals report a good working relationship.	Can independently work with Duke organizational areas and individuals to get things done, including issues that require complex coordination and understanding. Individuals and groups consistently report an excellent working relationship.

Reference: Details of Individual competencies

Research Operations	Screening		Screen participants for all studies, including those that are complex in nature (e.g., procedural and interventional studies).
	Recruitment		Employs strategies to maintain recruitment rates and evaluate processes to identify problems related to recruitment rates. Escalates issues.
	Subject management and retention		Employ strategies to maintain retention rates and evaluate processes to identify problem related to retention rates. Escalate issues.
	Subject-level documentation		Maintains subject-level documentation for all studies, including those that are complex in nature (e.g., procedural and interventional studies) and/or require DUHS billing.
	Prepare and conduct study visits		Conducts and plans for visits for all studies, including those that are complex in nature (e.g., procedural and interventional studies). May train junior staff, for non-complex studie
	Specimen collection and preparation		Collects, prepares, processes, ships, and maintains the inventory of research specimens f special samples (e.g., contagious specimens, international shipping, etc.).
	Investigational Products		Provides Investigational Product (IP) to research participants. Tracks IP compliance at the protocol- and subject-level. Determines the best methods for handling IP. Coordinates w investigational pharmacies as necessary. Manages IP, including arrival, storage, and handling. Serves as the primary liaison for IP with sponsors, IDS, and other parties as necessary.
	Study-level documentation	CORE	Maintain study level documentation for all studies, including those that are complex in nature (e.g., procedural and interventional studies) and/or require DUHS billing.
	Consent procedures (consent)		Conduct and document consent for participants in a variety of studies, including comple studies and/or those that require DUHS billing.
	Monitoring and Audits (audit)	CORE	Prepares for and provides support for study monitoring and study audit visits. Provides support for reviewer during visit. Addresses and corrects findings.

Research Operations	Interactions and submissions with IRB	CORE	Uses electronic submission system to submit new studies, amendments, continuing reviews, final reports, deviations, and/or events that require prompt reporting. Communicates with the IRB staff and reviewers to determine the best path for submissior and deal with issues or questions.
	Institutional Regulatory Policies and Processes	CORE	Recognizes when regulatory and institutional policies or processes are relevant, and applies appropriately.
	Institutional Regulatory Documentation	CORE	Prepares and completes all the components needed for ethics review (e.g. develop consent form, research summary).
	Contracts and Agreements		Recognizes when agreements (MTAs, CDAs, DUAs, DTAs, etc.) are necessary and alerts t study team.
	Regulatory compliance with international studies		Contacts appropriate agencies to conduct research internationally. Applies appropriate ethical guidelines across borders. Uses the appropriate documents and processes, and seeks necessary approvals and requirements for participating countries.
	Interacting with the FDA as it relates to Duke Investigator held IND/IDE		Prepares FDA regulatory submissions in collaboration with ORAQ, including preparation, submission, and maintenance of relevant documentation. Addresses FDA review and/or potential hold issues in collaboration with the Principal Investigator (PI).
	Technology Management		Seeks out ways to employ technology to optimize organizational and individual performance.
	Use and Development of SOPs		Develops or helps develop SOPs for implementation of research protocols.
	Team meetings and management (team)		Ability to lead meetings that are multidisciplinary including those with complex objective
	Electronic Management of Study Participants		Uses systems and system reports to manage patient/participant research activities and charge routing.

Ethics	Identification and Documentation of Adverse Events		Identifies all AEs, and determines whether or not they are reportable. Collaborates with the PI to determine AE attributes, including relatedness to study. Prepares the appropria documentation to be used in AE reporting.
	Adverse Event Reporting	CORE	Completes and submits adverse events reports, according to institution and sponsor-specific prompt reporting requirements.
Data/Informatics	Data flow		Maps a protocol's data flow plan including data capture, storage, transfer, management, quality, and preparation for analysis (may include data from EDCs, EHR, mobile apps, etc
	Data Collection and Entry		Enters or collects data for all studies, including those that are complex in nature. Develo data entry or collection protocols for non-complex studies. May provide oversight to stuc team members collecting, entering, or scoring data for non-complex studies. Implements EDCs or technology according to protocol.
	Data Security and Provenance	CORE	Recognizes and reports security of physical and electronic data vulnerabilities.
	Data Corrections, Queries, and QA		Corrects accuracy and completeness of data issues for individual studies. May oversee junior staff in investigating issues. Recognizes data quality trends and escalates as appropriate.
Scientific Concepts	Protocol development		Using scientific proposals from the PI, develops protocols for non-complex studies.
	Literature Reviews		Conducts literature searches and reviews.
	Research Design		Demonstrates a basic understanding of the elements of research study designs.
	Scholarly Publishing		Develops portions of scientific publications or presentations. Serves as co-author on poster presentations or publications.

	Proposal development		Assists with the development of research proposals.
Site & Study Management	Determining Participation in Trials		Collects information to determine whether the study team's participation in a specific tria is feasible.
	Managing Resources		Ensures that there are ample study supplies and ensures equipment is in good working order.
	Managing Risk	CORE	Ensure that study is conducted in compliance with institutional requirements and other policies. Oversee maintenance of Delegation of Authority Logs and training of KP on stuc specific duties.
	Site Visits and Sponsor Training		Participates in and prepares for site selection, initiation and monitoring meetings for Sponsor monitored studies.
	Operational Plans		Develop and follow protocol-specific systems and documents including process flows and standard operating procedures.
	Study Closeout	CORE	Prepare studies for closeout and document storage.