November 2018

ECRPTQ Clinical Research Professional Competencies

The University Of Michigan

Map of Clinical Research Professional (CRP) job skill descriptions to ECRPTQ Competency Domain Framework

Domain 1 - Scientific Concepts & Research Design						
Competency Statement	**Inventory items (Novice)**	**Inventory items (Apprentice)**	**Inventory items (Practitioner)**	**Inventory items (Expert)**	**Inventory items (Mentor)**	**Inventory items (Project Manager)**
3) Explain the elements of (statistical, epidemiological, operational) clinical and translational study design.	List the phases of clinical trials.	With supervision, identify the phase of a specified clinical trial.	Independently identify the phases of clinical trials.	Instruct study team members in identifying the phases of clinical trials.	Mentor study team members to identify the phases of clinical trials.	Evaluate study team members' understanding of a clinical trial and develop personnel training plans.

Domain 2 - Ethical & Participant Safety Considerations						
Competency Statement	**Inventory items (Novice)**	**Inventory items (Apprentice)**	**Inventory items (Practitioner)**	**Inventory items (Expert)**	**Inventory items (Mentor)**	**Inventory items (Project Manager)**
1) Differentiate between standard of care and clinical research activities	With supervision, perform assigned duties to address simple study participant concerns and issues.	Evaluate and prioritize simple study participant concerns and issues.	With assistance, evaluate and prioritize moderate study concerns and issues.	Independently evaluate and prioritize complex study concerns and issues.	Independently evaluate and prioritize complex study concerns and issues.	Supervise reconciliation of study concerns and issues.
	With supervision, list activities specific to a clinical research protocol.	With supervision, differentiate between standard of care and research activities specific to a clinical research protocol.	With assistance, develop a study billing calendar following U-M regulatory guidelines.	Develop a study billing calendar following U-M regulatory guidelines.	Provide expertise and assistance to study team members developing billing calendars.	Provide oversight for study billing calendars. Document study team member training for developing billing calendars.

Competency Statement	Inventory items (Novice)	Inventory items (Apprentice)	Inventory items (Practitioner)	Inventory items (Expert)	Inventory items (Mentor)	Inventory items (Project Manager)
1) Differentiate between standard of care and clinical research activities		Assist with reconciliation of financial accounts for study participants.	Assist with reconciliation of financial accounts for study participants.	Manage reconciliation of financial accounts for study participants.	Instruct study team members in reconciling financial accounts for study participants.	Manage reconciliation of research study financial accounts.
3) Compare the requirements for human subject protections and privacy under different national and international regulations and ensure their implementation throughout all stages of a clinical trial.	List the required elements of an informed consent document for IRB approval.	With supervision, create informed consent documents that include all required elements for IRB approval.	Create informed consent documents that include all required elements for IRB approval.	Provide expertise and guidance to study team members writing informed consent documents (including all required elements) for IRB approval.	Mentor study team members in writing informed consent documents that include all required elements for IRB approval.	Document that informed consent documents include all required elements for IRB approval. Create training plan for personnel writing informed consent documents.
	With assistance, locate and download current IRB-approved informed consent documents from IRB applications.	Locate and download current IRB-approved informed consent documents.	With supervision, upload informed consent documents to IRB applications.	Manage submission of informed consent documents to IRB applications.	Monitor IRB applications for documentation of current informed consent documents and revisions. Identify study participants for re-consenting in accordance with regulatory guidelines.	Manage submission of informed consent documents to IRB applications.

Competency Statement	Inventory items (Novice)	Inventory items (Apprentice)	Inventory items (Practitioner)	Inventory items (Expert)	Inventory items (Mentor)	Inventory items (Project Manager)
3) Compare the requirements for human subject protections and privacy under different national and international regulations and ensure their implementation throughout all stages of a clinical trial.	Watch study team members conducting informed consent interviews with research participants.	With supervision, employ regulatory and departmental guidelines to conduct informed consent interviews with research participants. ❖ Address essential elements of informed consent with potential participants ❖ Conduct informed consent interview with appropriate techniques to assess participant understanding	Employ regulatory and departmental guidelines to conduct informed consent interviews with research participants. ❖ Address essential elements of informed consent with potential participants ❖ Conduct informed consent interview with appropriate techniques to assess participant understanding	Teach study team members to conduct informed consent interviews with research participants following regulatory and departmental guidelines. ❖ Address essential elements of informed consent with potential participants ❖ Conduct informed consent interview with appropriate techniques to assess participant understanding	Provide guidance to study team members responsible for conducting informed consent interviews with research participants. ❖ Address essential elements of informed consent with potential participants ❖ Conduct informed consent interview with appropriate techniques to assess participant understanding	Supervise study team members conducting informed consent interviews with research participants.
	List the steps required to document the informed consent process according to U-M regulatory and departmental guidelines.	Document informed consent process according to regulatory guidelines.	Document informed consent process according to regulatory guidelines.	Document informed consent process according to regulatory guidelines.	Mentor study team members in documenting the informed consent process according to regulatory guidelines.	Supervise study team members documenting the informed consent process according to regulatory guidelines.

Competency Statement	Inventory items (Novice)	Inventory items (Apprentice)	Inventory items (Practitioner)	Inventory items (Expert)	Inventory items (Mentor)	Inventory items (Project Manager)
3) Compare the requirements for human subject protections and privacy under different national and international regulations and ensure their implementation throughout all stages of a clinical trial.	Explain use of placebo in a clinical trial.	Describe ethical considerations regarding use of placebos in a clinical trial.	Instruct study team members in the ethical use of placebos in a clinical trial.	Following protocol and PI instructions, implement use of placebo in a clinical trial.	Mentor study team members regarding ethical considerations in the use of placebos in clinical trials.	Evaluate need and document training for team members regarding ethical considerations in the use of placebos in clinical trials.
	Employ regulatory and department specific guidelines to ensure participant privacy and data confidentiality (e.g. HIPAA privacy rules).	Employ regulatory and department specific guidelines to ensure participant privacy and data confidentiality (e.g. HIPAA privacy rules).	Teach study team members to follow regulatory and department specific guidelines to ensure participant privacy and data confidentiality (e.g. HIPAA privacy rules).	Evaluate circumstances and determine when HIPAA privacy rules apply to research.	Provide guidance to study team members regarding HIPAA privacy rules.	Document process of following regulatory and department specific guidelines to ensure participant privacy and data confidentiality (e.g. HIPAA privacy rules).
		Explain ethical techniques for recruitment and retention of research study participants according to U-M and departmental regulatory procedures and guidelines.	With supervision, employ techniques for ethical recruitment and retention of research study participants according to regulatory procedures and guidelines.	Instruct study team members in techniques of ethical recruitment and retention of research study participants according to regulatory procedures and guidelines.	Mentor study team members in techniques of ethical recruitment and retention of research study participants according to regulatory procedures and guidelines.	Monitor study recruitment and retention activities for compliance with regulatory procedures and guidelines.

Competency Statement	Inventory items (Novice)	Inventory items (Apprentice)	Inventory items (Practitioner)	Inventory items (Expert)	Inventory items (Mentor)	Inventory items (Project Manager)
4) Explain the foundational documents that inform laws & guidelines for informed consent and the protection of human study participants.	Describe historical events that had significant impact on federal regulations for the protection of human subjects.	Describe historical events that had significant impact on federal regulations for the protection of human subjects.	Describe historical events that had significant impact on federal regulations for the protection of human subjects.	Describe historical events that had significant impact on federal regulations for the protection of human subjects.	Describe historical events that had significant impact on federal regulations for the protection of human subjects.	Describe historical events that had significant impact on federal regulations for the protection of human subjects.
5) Define vulnerable populations and additional safeguards needed for protection of those populations.	Watch study team members obtain informed consent from vulnerable populations (e.g. consent/ assent).	Explain regulatory and ethical considerations for obtaining informed consent from vulnerable populations (e.g. consent/ assent).	Apply regulatory and ethical considerations when obtaining informed consent from vulnerable populations (e.g. consent/ assent).	Teach study team members to apply regulatory and ethical considerations when obtaining informed consent from vulnerable populations (e.g. consent/ assent).	Evaluate and mentor study team members in the process of obtaining informed consent from vulnerable populations (e.g. consent/ assent).	Asses studies for inclusion of vulnerable populations. Evaluate ability of study team members to obtain informed consent from vulnerable populations and provide recommendations for training.
8) Summarize the principles and methods of distributing risk and benefit through selection and management of clinical trial participants.	Complete training for study participant registry.	With supervision, complete and activate study participant postings.	Independently complete and activate study participant postings.	Teach study team members to complete and activate study participant postings.	Mentor study team members in completing and activating study participant postings in.	Monitor and document study team members' use of study participant registry.

Competency Statement	Inventory items (Novice)	Inventory items (Apprentice)	Inventory items (Practitioner)	Inventory items (Expert)	Inventory items (Mentor)	Inventory items (Project Manager)
	With supervision, identify potential study participants.	With supervision, identify potential study participants.	Independently identify potential study participants.	Independently identify and contact potential study participants.	Mentor study team members in identifying potential study participants.	Monitor and document contact with potential research study participants.

Domain 3 - Investigational Products Development & Regulation						
Competency Statement	**Inventory items (Novice)**	**Inventory items (Apprentice)**	**Inventory items (Practitioner)**	**Inventory items (Expert)**	**Inventory items (Mentor)**	**Inventory items (Project Manager)**
2) Describe the regulatory responsibilities of the various institutions participating in the investigational product development process.		With assistance, describe the responsibilities of study team members in the IND/IDE process.	Describe the responsibilities of study team members in the IND/IDE process.	Demonstrates experience with pharmaceutical trials/CROs	Instruct study team members on role shifts when an investigator initiates an IND/IDE study.	Monitor roles of sponsor, monitor, and investigators in IND/IDE studies
6) Describe the safety reporting requirements of regulatory agencies both pre- and post-approval.			With supervision, follow regulations for the receipt, storage, dispensing, destruction and accountability of investigational products.	Independently follow regulations for the receipt, storage, dispensing, destruction, and accountability of investigational products.	Instruct study team members in following regulations for the receipt, storage, dispensing, destruction, and accountability of investigational	Oversee and document the management of investigational products following state and federal regulations for study product management.

Domain 4 - Clinical Trials Operations (GCPs)						
Competency Statement	**Inventory items (Novice)**	**Inventory items (Apprentice)**	**Inventory items (Practitioner)**	**Inventory items (Expert)**	**Inventory items (Mentor)**	**Inventory items (Project Manager)**
1) Evaluate the conduct and management of clinical trials.	Complete IRB application training.	Complete IRB application training.	Complete IRB application training.	Complete IRB application training.	Complete IRB application training.	Complete IRB application training.
	With supervision, assist in completing simple IRB study applications and uploading documentation.	With supervision, complete simple IRB study applications and upload documentation.	With PI input and approval, complete moderately complex IRB study applications and upload documentation.	Independently complete complex IRB study applications and upload documentation for PI approval and submission.	Provide guidance to study team members completing and uploading IRB application documents.	Ensure IRB study applications are complete and all necessary documents uploaded for PI approval and submission.
				Assess and remedy contingencies from IRB.	Assess and remedy contingencies from IRB.	Assess and remedy contingencies from IRB.
	With supervision, complete assigned tasks for a clinical trial according to regulatory guidelines.	Assist in managing 1-2 simple clinical trials according to regulatory guidelines.	Coordinate and manage 1-2 moderately complex clinical trials according to regulatory guidelines.	Coordinate and manage multiple highly complex clinical trials according to regulatory guidelines.	Provide guidance to study team members managing clinical trials.	Supervise and manage clinical trials operations.

Competency Statement	Inventory items (Novice)	Inventory items (Apprentice)	Inventory items (Practitioner)	Inventory items (Expert)	Inventory items (Mentor)	Inventory items (Project Manager)
1) Evaluate the conduct and management of clinical trials.	Define the purpose of the CTN number.	Identify the CTN number from ClinicalTrials.gov and describe how it is recorded in the IRB application.	Obtain a CTN number from ClinicalTrials.gov and record it in the IRB application.	Instruct study team members in obtaining a CTN number from ClinicalTrials.gov and recording it in the IRB application.	Provide guidance to study team members who use ClinicalTrials.gov.	Ensure use of ClinicalTrials.gov according to U-M regulatory guidelines.
2) Describe the roles and responsibilities of the clinical investigation team as defined by GCP guidelines.	With assistance, identify the responsibilities of research institutes and regulatory agencies in conducting research.	Identify the responsibilities of research institutes and regulatory agencies in conducting research.	Instruct study team members in identifying the responsibilities of research institutes and regulatory agencies in conducting research.	Instruct study team members in identifying the responsibilities of research institutes and regulatory agencies in conducting research.	Provide guidance to study team members regarding the responsibilities of research institutes and regulatory agencies in conducting clinical research.	Create organizational plan to document roles and responsibilities of all study team members
3) Evaluate the conduct and documentation of clinical trials as required for compliance with GCP guidelines	With supervision, identify the required elements of a clinical trial protocol.	With assistance, identify and utilize the required elements of a research study protocol to apply best practices to conduct research according to U-M and departmental regulatory guidelines.	Independently identify and utilize information from a research study protocol to develop an operational plan for a research study.	Instruct study team members in identifying the required elements of a clinical trial protocol needed to develop an operation plan for a research study.	Mentor study team members in identifying the required elements of a clinical trial protocol needed to develop an operation plan for a research study.	Interpret protocol structure and study requirements to ensure compliance and safety during implementation of a clinical trial.

Competency Statement	Inventory items (Novice)	Inventory items (Apprentice)	Inventory items (Practitioner)	Inventory items (Expert)	Inventory items (Mentor)	Inventory items (Project Manager)
3) Evaluate the conduct and documentation of clinical trials as required for compliance with GCP guidelines	With supervision, access information from the electronic medical record (EMR).	Independently access information from the electronic medical record (EMR).	Use information from the electronic medical record to meet research study requirements.	Instruct study team members in abstracting information from the electronic medical record (EMR) to meet research study requirements.	Provide guidance to study team members using the electronic medical record (EMR) to ensure compliance with U-M regulatory guidelines.	Supervise and manage study procedures to comply with U-M regulatory reporting requirements.
5) Describe appropriate control, storage, and dispensing of investigational products	**See Investigational Products category**	**See Investigational Products category**	**See Investigational Products category**	**See Investigational Products category**	**See Investigational Products category**	**See Investigational Products category**
6) Differentiate the types of adverse events (AEs) that occur during clinical trials, understand the identification process for AEs, and describe the reporting requirements to IRBs/IECs, sponsors, and regulatory authorities	With assistance, define ORIO (otherwise reportable incidence or occurrence) and Adverse Event (AE) categories according to regulatory and sponsor guidelines.	Independently define ORIO (otherwise reportable incidence or occurrence) and Adverse Event (AE) categories according to regulatory and sponsor guidelines.	With PI assistance, identify exceptional situations (including AEs/ORIOS/protocol deviations) following regulatory procedures and sponsor guidelines.	Instruct study team members in identifying study-specific exceptional situations (including AEs/ORIOS/protocol deviations) following regulatory procedures and sponsor guidelines.	Provide guidance to study team members in identifying study-specific exceptional situations (including AEs/ORIOS/protocol deviations) following regulatory procedures and sponsor guidelines.	Supervise and manage reports of study-specific exceptional situations (including AEs/ORIOS/protocol deviations) following regulatory procedures and sponsor guidelines.

Competency Statement	Inventory items (Novice)	Inventory items (Apprentice)	Inventory items (Practitioner)	Inventory items (Expert)	Inventory items (Mentor)	Inventory items (Project Manager)
6) Differentiate the types of adverse events (AEs) that occur during clinical trials, understand the identification process for AEs, and describe the reporting requirements to IRBs/IECs, sponsors, and regulatory authorities	Define the process for reporting exceptional situations during implementation of a research study.	With supervision, report exceptional situations during implementation of a research study including adverse events, serious adverse events, and otherwise reportable incidence or occurrence according to regulatory procedures and sponsor guidelines.	Independently report exceptional situations (including AEs/ORIOS/protocol deviations) following regulatory procedures and sponsor guidelines.	Instruct study team members on process of reporting exceptional situations (including AEs/ORIOS/protocol deviations) following regulatory procedures and sponsor guidelines.	Provide guidance to study team members in reporting study-specific exceptional situations (including AEs/ORIOS/protocol deviations) following regulatory procedures and sponsor guidelines.	Manage safety issues under guidance of the Principal Investigator.
9) Describe the purpose and process for monitoring of a study.	Perform assigned tasks for monitor visit preparation.	With supervision, assist with monitor visit preparation.	With supervision, plan and participate in monitor visits.	Independently plan and participate in monitor visits.	Provide guidance to study team members planning for monitor visits.	Supervise the planning and preparation of monitor visits.
	Follow standard practice guidelines (SPG) for monitoring visits	Follow standard practice guidelines (SPG) for monitoring visits	With supervision, assist in creating standard practice guidelines (SPG) for monitor visits.	Assess study activities for compliance with monitor visit standard practice guidelines (SPG).	Provide instruction and support to study team members creating standard practice guidelines (SPG) for monitoring visits.	Supervise the creation and implementation of standard practice guidelines (SPG) for monitor visits.

Competency Statement	Inventory items (Novice)	Inventory items (Apprentice)	Inventory items (Practitioner)	Inventory items (Expert)	Inventory items (Mentor)	Inventory items (Project Manager)
9) Describe the purpose and process for monitoring of a study.				Meet with external monitors to review findings and maximize clinical trial performance.	Create training plan based on external monitor findings to maximize clinical trial performance.	Meet with external monitors to review findings and maximize clinical trial performance.
	With supervision, implement recommendations from monitoring reports.	With supervision, implement recommendations from monitoring reports.	Independently implement recommendations from monitoring reports.	Develop monitoring reports to document findings.	Share monitoring reports with study team members and explain findings.	Manage monitoring reports.
10) Describe the purpose and process of clinical trial audits	Perform assigned tasks for audit visit preparation.	With supervision, assist with audit visit preparation.	With supervision, plan and participate in internal and external audits.	Independently plan and participate in internal and external audits.	Provide guidance to study team members planning for internal and external audits.	Manage internal and external audits.
	With supervision, gather data related to protocol deviations and adverse events.	With supervision, implement corrective action plans for protocol deviations that increase the risk of noncompliance.	Independently implement corrective action plans for protocol deviations that increase the risk of noncompliance.	With PI assistance, develop a response plan to address resolution of protocol deviations and action items.	Teach study team members to recognize protocol deviations and assist in implementing corrective action plans.	Oversee implementation of response plans to address resolution of protocol deviations and action items.
11) Describe the safety reporting requirements of regulatory agencies both pre- and post-approval	Complete IATA training.	Complete IATA training.	Complete IATA training.	Maintain bi-yearly IATA training.	Maintain bi-yearly IATA training.	Oversee and document IATA training for study team members.

Competency Statement	Inventory items (Novice)	Inventory items (Apprentice)	Inventory items (Practitioner)	Inventory items (Expert)	Inventory items (Mentor)	Inventory items (Project Manager)
11) Describe the safety reporting requirements of regulatory agencies both pre- and post-approval	With supervision, perform assigned tasks for specimen management (includes collection, labeling, processing, storing, packing, shipping and tracking).	With supervision, perform specimen management tasks to maintain integrity with regulatory procedures (includes collection, labeling, processing, storing, packing, shipping and tracking).	Independently perform specimen management tasks to maintain integrity with regulatory procedures (includes collection, labeling, processing, storing, packing, shipping and tracking).	Supervise specimen management process to maintain integrity with regulatory procedures (includes collection, labeling, processing, storing, packing, shipping and tracking).	Instruct study team members in utilizing regulatory procedures to maintain integrity of specimen management (includes collection, labeling, processing, storing, packing, shipping and tracking).	Oversee and document the specimen management process for a clinical trial utilizing regulatory procedures to maintain integrity of specimen management (includes collection, labeling, processing, storing, packing, shipping and tracking).
	With supervision, collect and maintain specimen collection materials.	Manage specimen kit inventory, storage, and expiration tracking.	Assist with regulatory responsibilities for biosafety monitoring and inspections.	Apply regulatory requirements for biosafety monitoring and inspections.	Instruct study team members in specimen kit management according to biosafety regulatory requirements.	Manage and document regulatory requirements for biosafety monitoring and inspections.

Domain 5 - Study and Site Management						
Competency Statement	**Inventory items (Novice)**	**Inventory items (Apprentice)**	**Inventory items (Practitioner)**	**Inventory items (Expert)**	**Inventory items (Mentor)**	**Inventory items (Project Manager)**
2) Develop and manage the financial and personnel resources necessary to conduct a clinical research study.	With assistance, follow a study budget.	With assistance, build a study budget.	Assess research study budgets for completeness and accuracy.	With PI supervision, develop and manage a clinical trial protocol budget in compliance with institutional, sponsor and federal regulations.	Assist study team members in maintaining budget compliance according to institutional, sponsor and federal regulations.	Assess study budget requirements and develop a plan to meet study obligations.
	Perform work plan assignments with supervision.	With supervision, implement work plan.	Propose effort requirements for a new research study.	Recommend study team workload assignments and distribution.	Assist with preparation of a feasibility assessment.	Provide oversight of study team personnel related to study activity and accurate reporting within the CTMS/Billing calendar.
			Identify study project strengths and weaknesses and assist in providing solutions.	Provide input in negotiated contract language related to study implementation in industry sponsored clinical trials.	Assist study team members in identifying project strengths and weaknesses and providing solutions.	Approve work plan and research study budget assessment. Provide input in negotiated contract language.

Competency Statement	Inventory items (Novice)	Inventory items (Apprentice)	Inventory items (Practitioner)	Inventory items (Expert)	Inventory items (Mentor)	Inventory items (Project Manager)
3) Utilize project management body of knowledge to assess and define processes and training for quality improvement in clinical trial site management.	With supervision, identify resources needed to complete tasks.	Independently identify resources needed to complete tasks.	Perform moderately complex procedures independently (skin biopsies, hair plucking, venipuncture, etc. w/MCRU training).	Perform and teach highly complex procedures independently (skin biopsies, hair plucking, venipuncture, etc. w/MCRU training).	Assess study team member training needs and develop learning plans.	Evaluate impact of study team training to assess outcome of quality initiatives.
4) Utilize project management body of knowledge to manage participant recruitment and track study progress.	**See Ethical & Participant Safety**	**See Ethical & Participant Safety**	**See Ethical & Participant Safety**	**See Ethical & Participant Safety**	**See Ethical & Participant Safety**	**See Ethical & Participant Safety**
	With supervision, schedule study participants for research visits and follow-up appointments.	Independently enroll research study participants following U-M regulatory and departmental guidelines.	Track enrollment progress and assist in making adjustments to the recruitment plan.	Create and implement participant recruitment, retention, and study management plans.	Assist study team members in enrolling research study participants following U-M regulatory and departmental guidelines.	Create and implement participant recruitment, retention, and study management plans.
	With supervision complete and document assigned study procedures including collection of external medical records and radiology films.	Independently utilize study calendars to follow and document completion of study procedures.	Evaluate a protocol and recommend workflow modifications to improve efficiency.	Using a protocol, track study milestones and make needed adjustments.	Teach study team members to use a protocol to track study milestones.	Identify and resolve potential study implementation issues.

Competency Statement	Inventory items (Novice)	Inventory items (Apprentice)	Inventory items (Practitioner)	Inventory items (Expert)	Inventory items (Mentor)	Inventory items (Project Manager)
4) Utilize project management body of knowledge to manage participant recruitment and track study progress.	With supervision, administer simple questionnaires and online surveys according to regulatory and departmental guidelines.	With supervision, administer moderately complex questionnaires and online surveys according to regulatory and departmental guidelines.	Independently administer moderately complex questionnaires and online surveys according to regulatory and departmental guidelines.	Assume delegated duties from the Principal Investigator to provide results, not interpretation, to study participants or health care providers.	Assist study team members in collecting and completing data collection forms according to regulatory guidelines.	Function as a liaison between study participants and investigators, providing results, not interpretation, to study participants or health care providers.
5) Meet the legal and regulatory responsibilities, liabilities, and accountabilities that are involved in the conduct of clinical trials.	With assistance, identify the sections of a regulatory binder and define the concept of source documents	Independently identify essential source documents.	Independently implement and follow recommended file system for a regulatory binder.	Monitor development a regulatory binder following federal guidance for recommended file systems.	Assist study team members in compiling documentation requirements for a clinical trial.	Monitor development a regulatory binder following federal guidance for recommended file systems.
	With supervision, assist with collection and completion of regulatory materials for studies including CLIAs and CAPs .	Assist with collection and completion of regulatory materials for studies including CLIAs and CAPs .	Independently create and post studies in ClinicalTrials.gov.	Independently create and post studies in ClinicalTrials.gov.	Assist study team members in creating and posting studies in ClinicalTrials.gov.	Monitor and maintain postings in ClinicalTrials.gov.

Competency Statement	Inventory items (Novice)	Inventory items (Apprentice)	Inventory items (Practitioner)	Inventory items (Expert)	Inventory items (Mentor)	Inventory items (Project Manager)
6) Identify and explain the specific procedural, documentation, and oversight requirements of PIs, sponsors, CROs, and regulatory authorities related to the conduct of a clinical trial.	With assistance, describe significance and use of a 1572 and 1571 form.	Describe significance and use of a 1572 and 1571 form.	Maintain complete 1572 and develop 1571 forms with supervision.	Develops and maintains complete 1572 and 1571 forms.	Maintain complete 1572 and 1571 forms.	Maintain complete 1572 and 1571 forms.
	Explain purpose of a delegation of duty log and define who is responsible for signing and maintenance.	Explain purpose of a delegation of duty log and define who is responsible for signing and maintenance.	Create and maintain Delegation of Authority log with signatures according to federal regulatory guidelines.	Identify investigator responsibilities in conducting a study and oversight of delegated tasks to research personnel.	Train study team members in identifying investigator oversight of delegated tasks.	Identify investigator responsibility in conducting a study and oversight of delegated tasks to research personnel.

Domain 6 - Data Management and Informatics						
Competency Statement	**Inventory items (Novice)**	**Inventory items (Apprentice)**	**Inventory items (Practitioner)**	**Inventory items (Expert)**	**Inventory items (Mentor)**	**Inventory items (Project Manager)**
2) Describe the typical flow of data throughout a clinical research study.	With supervision, complete simple data collection forms using source data.	With supervision, complete moderately complex data collection forms using source data.	Independently complete all levels of data collection forms using source data.	Design case report forms, study documents, and tools.	Train and assist study team members in creating case report forms and data collection tools.	Oversee process of creating case report forms and data collection.
	With supervision, enter study data into an electronic database.	Independently enter study data into an electronic database.	Apply procedures for data security and storage according to regulatory policies.	With assistance, provide oversight for data quality and management.	Provide training and assistance to study teams in assessing data quality and safety procedures.	With PI assistance, provide oversight for data quality and management.
3) Summarize the process of electronic data capture and the importance of information technology in data collection, capture, and management.	Complete clinical trial management system (CTMS) training.	Complete clinical trial management system (CTMS) training.	Utilize clinical trial management system (CTMS) or other software to track ongoing study progress.	Utilize clinical trial management system (CTMS) or other software to track ongoing study progress.	Train study team members to use a clinical trial management system (CTMS).	Manage and document use of a clinical trial management system (CTMS).

Competency Statement	Inventory items (Novice)	Inventory items (Apprentice)	Inventory items (Practitioner)	Inventory items (Expert)	Inventory items (Mentor)	Inventory items (Project Manager)
	Complete electronic medical record (EMR) training.	With supervision, utilize the electronic medical record to screen participants for study eligibility & enroll in database according to regulatory guidelines.	Independently utilize the electronic medical record to screen participants for study eligibility & enroll in database according to regulatory guidelines.	Assess study team members use of the electronic medical record to screen participants for study eligibility & enroll in database according to regulatory guidelines.	Train study team members in screening participants for study eligibility using the electronic medical record.	Assess and manage study team members use of the electronic medical record to screen participants for study eligibility & enroll in database according to regulatory guidelines.
4) Describe the ICH GCP requirements for data correction and queries.	Identify how to record screening failures in the CTMS or create a screening log.	Independently resolve simple data queries.	Assess data queries, audits, and monitoring reports for trends in study deviations and violations.	Complete complex data queries/reports from the database and independently resolve issues.	Create and implement training plans for study team members performing data queries, audits, and monitoring reports	Create and implement process to address study deviations and violations according to regulatory procedures.
5) Describe the significance of data quality assurance system for scientific validity.				Track study metrics for quality assessments.	Evaluate impact of study team training to assess outcome of quality initiatives.	Demonstrate compliance with a corrective action plan for documented deviations.

Domain 7 - Leadership and Professionalism						
Competency Statement	**Inventory items (Novice)**	**Inventory items (Apprentice)**	**Inventory items (Practitioner)**	**Inventory items (Expert)**	**Inventory items (Mentor)**	**Inventory items (Project Manager)**
1) Apply the principles and practices of leadership, management, and mentorship within the clinical research environment.			Assist in providing training to study team members.	Independently provide study team member training for complex studies.	Assess study team member training needs and develop training plans.	Develop and monitor training plans.
				Conduct research related team meetings.	Conduct research related team meetings.	Conduct research related team meetings.
2) Identify and implement procedures for the prevention or management of the ethical and professional conflicts of interest that are associated with the conduct of clinical research.	**See Ethical & Participant Safety section**	**See Ethical & Participant Safety section**	**See Ethical & Participant Safety section**	**See Ethical & Participant Safety section**	**See Ethical & Participant Safety section**	**See Ethical & Participant Safety section**
3) Identify and apply the professional guidelines and codes of ethics that apply to the conduct of clinical research.	With supervision, follow regulatory and department specific guidelines to ensure participant privacy and data confidentiality (e.g. HIPAA privacy rules).	Employ regulatory and department specific guidelines to ensure participant privacy and data confidentiality (e.g. HIPAA privacy rules).	Employ regulatory and department specific guidelines to ensure participant privacy and data confidentiality (e.g. HIPAA privacy rules).	Employ regulatory and department specific guidelines to ensure participant privacy and data confidentiality (e.g. HIPAA privacy rules).	Employ regulatory and department specific guidelines to ensure participant privacy and data confidentiality (e.g. HIPAA privacy rules).	Employ regulatory and department specific guidelines to ensure participant privacy and data confidentiality (e.g. HIPAA privacy rules).

Domain 8 - Communication and teamwork						
Competency Statement	**Inventory items (Novice)**	**Inventory items (Apprentice)**	**Inventory items (Practitioner)**	**Inventory items (Expert)**	**Inventory items (Mentor)**	**Inventory items (Project Manager)**
1) Discuss the relationship and appropriate communication between sponsor, CRO, and clinical research site. 2) Describe the component parts of a traditional scientific publication. 3) Effectively communicate the content and relevance of clinical research findings to colleagues, advocacy groups, and the non-scientist community. 4) Describe methods necessary to work effectively with multidisciplinary and inter-professional research teams.	**No CRC items in this category**	**No CRC items in this category**	**No CRC items in this category**	**No CRC items in this category**	**No CRC items in this category**	**No CRC items in this category**