UCDAVIS HEALTH | Clinical and Translational Science Center

Clinical Research Coordinator (CRC) Foundations Training Program

Course Schedule and Due Dates

Week	Topics and Learning Objectives	Assignments/ Homework - (Due Sunday at 11:59 p.m. each week.)
Week 1	**Clinical Research Coordinator Core Competency Foundations Overview and Training Plan** • Describe the overall flow and format of the training program. • Discuss some of the general principles of Good Clinical Practices (GCPs). • Explain what it means to be competent and the expectations for CRC competency: Overarching knowledge, skills, and abilities and Specific competencies as they relate to supporting the Principal Investigator (PI) in fulfilling International Council for Harmonization (ICH) GCP responsibilities.	• Reflective learning post. • Field trip preparation question – CTSC Clinical Research Center (CCRC). • Weekly Feedback Survey • Review Infographic: Clinical Research Relationships and Documents. • Complete Introduction to Clinical Trials (Association of Clinical Research Professionals (ACRP) eLearning). • Complete The Drug Development Process: Improving Trial Feasibility and Exploring Your Growth Potential (ACRP eLearning).
Week 2	**Clinical Research Orientation 101** • Describe the clinical trial process. • Describe the different study designs and aspects of the protocol. • Identify relevant aspects of the Chronic Obstructive Pulmonary Disease (COPD) case study protocol. • Explain the drug development process. • Explain the stakeholders contributing to the drug development process. • Describe the general roles and responsibilities of the study personnel. *Field Trip to the CTSC Clinical Research Center (CCRC).*	• Reflective learning post. • Field trip preparation question – Radiology. • Weekly Feedback Survey • Shadowing Worksheet (non-UC Davis Health Employee students only) • Complete Investigator Responsibilities (ACRP eLearning). • Complete Form FDA 1572: Getting it Right the First Time (ACRP eLearning). • Review Infographic: Focus on Supporting Adequate Principal Investigator (PI) Oversight.

Week 3	**PI Oversight** • Describe the investigator oversight process and requirements. • Explain the purpose of the Delegation of Authority (DOA) Log. • Determine if the CRC is qualified to perform requested duties. *Field trip with the Radiology department.*	• Reflective learning post. • Field trip preparation question – Clinical Trials Office (CTO) Complion Admin Team. • Weekly Feedback Survey • Shadowing Worksheet (non-UC Davis Health Employee students only) • Review Infographic: Focus on the Accurate and Timely Management of Essential Documents.

Week 4	**Maintain and Retain Essential Trial Documents**
	• Describe the required essential documents for a clinical trial.
	• Identify which essential documents are required for different stages of study protocol.
	Field trip with the CTO Complion Admin team.
		• Reflective learning post.
		• Field trip preparation question – RedCap team.
		• Weekly Feedback Survey
		• Shadowing Worksheet (non-UC Davis Health Employee students only)
		• Review Infographic: Focus on Proper Data Collection
		• Read FDA Guidance Documents:
		  ○ Electronic Source Data in Clinical Investigations
		  ○ Use of Electronic Health Record Data in Clinical Investigations

Week 5	**Everything You Need to Know about ALCOA-C!**
	• Define and describe different types of source documents.
	• Discuss the elements of ALCOA-C+ and recognize situations in which these principles have been compromised.
	• Define and describe different types of Case Report Forms.
	Field trip with the RedCap team.
		• Reflective learning post.
		• Field trip preparation question – IRB.
		• Weekly Feedback Survey.
		• Shadowing Worksheet (non-UC Davis Health employee students only)
		• Review Infographic: Focus on Institutional Review Board (IRB) Records and Reports
		• Read FDA Guidance Documents:
		  ○ IRB Continuing Review after Clinical Investigation Approval
		  ○ Using a Centralized IRB Review Process in Multicenter Clinical Trials

Week 6	**IRB Communications and Records and Reports** • Determine which reports are to be submitted to the IRB and the timeframe for submitting them. • Assess whether versions of documents (protocol, informed consent form, patient- facing materials) are appropriate to be used based on the status of IRB approval. • Distinguish between issues that require IRB notification from those that don't. *Class + field trip led by IRB education lead.*	• Reflective learning post. • Field trip preparation question – CTO Feasibility Team. • Weekly Feedback Survey. • Shadowing Worksheet (non-UC Davis Health employee students only) • Review Infographic: Focus on Site Qualifications • Complete Understanding Clinical Trial Protocols: Key Considerations for Effective Development and Feasibility Review (ACRP eLearning). • Complete Trial Feasibility and Selection: Their Impact on Accrual (ACRP eLearning).
Week 7	**Study Feasibility and Site Selection** • Describe the feasibility assessment process from the site and sponsor perspectives. • Discuss the criteria/factors that influence a site's willingness to conduct/accept a new study opportunity. • Explain the site qualification/selection process. *Field trip with the CTO Feasibility team.*	• Reflective learning post. • Field trip preparation question – StudyPages Team. • Weekly Feedback Survey. • Shadowing Worksheet (non- UC Davis Health employee students only) • Complete Improving Recruitment, Accrual, and Retention in Clinical Trials (ACRP eLearning). • Complete Using Metrics to Improve Subject Recruitment and Retention (ACRP eLearning). • Review Infographic: Focus on Validating Enrollment Potential. • Review Infographic: Focus on Subject Recruitment, Retention, and Compliance.

Week 8	**Patient Recruitment/Retention 101** • Describe the subject recruitment and retention process. • Discuss regulatory and ethical considerations relating to the recruitment and payment of clinical trial subjects. • Explain the importance of, and process for validating the investigator's enrollment potential. • Discuss common enrollment performance metrics. • Uncover potential reasons for subject withdrawal without coercing the subject to remain in the trial. *Field trip with StudyPages.*	• Reflective learning post. • Weekly Feedback Survey. • Shadowing Worksheet (non-UC Davis Health employee students only) • Complete ACRP Good Clinical Practice (GCP) Simulation (ACRP eLearning). • Complete Ethics and Human Subject • Protection: A Comprehensive Introduction (ACRP eLearning). • Complete Informed Consent • Simulation Training (ACRP eLearning). • Review Infographic: Focus on • Informed Consent Implementation and Documentation.
Week 9	**Informed Consent Process and Documentation** • Describe a regulatory and ethical informed consent process and associated documentation. • Discuss the circumstances under which re- consent is required. • Explain the difference between standard of care and research. • Describe the elements and purpose of GCPs. • Describe the factors supporting human subject's protection. • Explain the concepts of clinical equipoise/therapeutic misconception. • Recognize scenarios in which GCPs have not been adhered to.	• Reflective learning post. • Field trip preparation question – IDS. • Weekly Feedback Survey. • Shadowing Worksheet (non-UC Davis Health employee students only) • Review Infographic: Focus on Investigational Product Management. • Review Sample Investigational Product (IP) Management SOP and Temperature Log

Week 10	**IP Management and Accountability 101** • Describe the type of treatment assignments and treatment allocation procedures. • Describe IP shipment, storage, inventory management, expiration and destruction/ return processes. • Explain factors involved in subject education surrounding the proper storage and use of IP. • Describe the IP accountability process. *Field trip with the Investigational Drug Service (IDS) Team.*	• Reflective learning post. • Field trip preparation question – CTO Finance. • Weekly Feedback Survey. • Shadowing Worksheet (non-UC Davis Health employee students only) • Mastering the Event Reporting Cycle: Understanding Your Impact on Subject Safety (ACRP eLearning). • Review Infographic: Focus on Appropriate and Timely Reporting of Adverse Events. • Read FDA Guidance Document – Adverse Event Reporting to the IRBs.
Week 11	**Subject Safety Management Check-In!** • Define the types of adverse events (AEs) and processes for capturing, assessing, and reporting AEs. • Describe the regulatory reporting requirements for unanticipated problems and safety issues. *Field trip with the CTO Finance team.*	• Reflective learning post. • Field trip preparation question – Compliance Team. • Weekly Feedback Survey. • Shadowing Worksheet (non-UC Davis Health employee students only) • Complete Key Skills for Ensuring Quality Control through Risk-Based Decision Making (ACRP eLearning). • Complete Building Quality Management Systems for Sites and Sponsors: Root Causes and Corrective and Preventive Action (CAPA) (ACRP eLearning). • Review Infographic: Protocol and GCP Compliance Management. • Review Infographic: Quality Management Approaches and Monitoring Practices. • Read FDA Guidance Document Q9 Quality Risk Management.

Week 12	**Protocol/GCP Compliance and Monitoring Overview and CAPAs and Root Cause Analysis** • Define and discuss the range of protocol deviations. • Recognize scenarios in which GCPs and the protocol have not been adhered to. • Describe the monitoring process and the sponsor's obligations to monitor clinical trials. • Describe the role of the Clinical Research Associate (CRA)/ Study Monitor. • Explain the role of the CRC in supporting the monitoring process and how the CRC interacts with the CRA through the course of the trial. • Define CAPA terminology. • Describe CAPA basics (methodology and documentation). *Field trip with the Compliance team.*	• Reflective learning post. • Field trip preparation question – Electronic Medical Records (EMR) Research Team. • Weekly Feedback Survey. • Shadowing Worksheet (non-UC Davis Health Employee students only) • Journal of Best Practices – Notes to File Articles. • Complete eResearch: Managing Clinical Trials in an Electronic Environment.
Week 13	**Optimizing Study Communications – Best Practices** • Discuss different ways that study communications take place. • Define and explain considerations relating to Notes to File (NTF). • Describe study communication best practices. *In-class field trip with EMR Research team.*	• Reflective learning post. • Field trip preparation question – CTO CRCs. • Weekly Feedback Survey. • Shadowing Worksheet (non-UC Davis Health employee students only) • Read Clinical Research Article: The Anatomy of a Great Clinical Research Coordinator.
Week 14	**Pulling it All Together: A Day in the Life of a CRC** • Describe the considerations that influence daily prioritization of a busy CRC's tasks. • Practice prioritizing tasks based on real-life scenarios. *Field trip with CTO CRCs.*	• Reflective learning post. • Field trip preparation question – Pathology. • Weekly Feedback Survey. • Shadowing Worksheet (non-UC Davis Health employee students only)

Week 15	**Core Competency Training and Wrap-Up** • Review all course content and prepare for Entry-Level Knowledge Assessment (ELKA). • Complete the competency development and assessment worksheet and reflect on gaps and future training needs. *In-class field trip with the Pathology team.*	• Reflective Learning Post. • Weekly Feedback Survey. • Study for ELKA Exam. • Shadowing Worksheet (non-UC Davis Health Employee students only)
Week 16	ELKA Exam and Course Feedback Survey	• N/A