UNC School of Medicine

Clinical Trialist Training Program

Sponsored by NC TraCS and SOM CRSO

Clinical Trials 101 Bootcamp
Course Agenda

Session 1 Identifying Key Players & Resources ◦ Evaluating Opportunities & Planning for New Studies	
4:00 – 4:20	**Introductions** • Course overview • Clinical trials at UNC
4:20 – 4:40	**NC TraCS and CRSO** • Services and resources
4:45 – 5:45	**Research Opportunities & Workflow Development** • Initial study considerations • Comprehensive feasibility assessments • Other resource considerations
Session 2 General Elements of Study Start-up	
4:00 – 4:45	**Budget Preparation** • Understanding billing coverage analysis • Budget considerations and financial implications • Common pitfalls and examples • Assessing financial feasibility
4:50 – 5:20	**Contract Review & Execution** • UNC contract offices • Process overview
5:20 – 5:50	**IRB Application** • Application process and review types • Reporting to IRB • Conflict of interest disclosures and reviews
Session 3 PI Responsibilities ◦ Participant Recruitment & Engagement	
4:00 – 4:15	**Getting Started** • Finalizing and testing workflows • Planning for continuous study oversight
4:15 – 4:45	**PI Responsibilities** • FDA 1572 • Physician vs. physician scientist • Overview of requirements to various governing bodies • Common challenges
4:50 – 5:20	**Participant Recruitment** • Assessing recruitment feasibility • Developing a recruitment plan • Methods of participant recruitment and special considerations
5:20 – 5:50	**Participant Engagement and Informed Consent** • Research consent vs. clinical consent

	• Obtaining and maintaining informed consent • Best practices and special considerations
<u>Session 4</u> Monitoring & Overseeing the Study	
4:00 – 4:15	**Protocol Adherence & Data Management** • Appropriate protocol adherence • Data collection and sharing • Managing trial administrative data
4:15 – 4:30	**Adverse Events & Protocol Deviations** • Assessing and reporting adverse events • PI responsibilities • Guidelines and expectations for protocol deviations
4:30 – 5:00	**Site Visits** • Roles and expectations • Monitoring visits and audits • Common findings
5:05 – 5:30	**Coordinator/Staff Oversight** • Overview of roles and expectations • Appropriate hiring, management, and delegation