Clinical Trials 101 Bootcamp

Draft Syllabus

Goal

- To provide new site Principal Investigators (PI) and/or interested clinical trialists with a high-level overview of PI responsibilities and the basics of conducting federally-funded and corporate-sponsored clinical trials.

Audience

- New site PIs, new investigators, interested clinical trialists, or current PIs who need additional support or a refresher on elements of conducting a clinical trial
- Clinically-focused personnel – faculty/physicians/residents/fellows

Format

- Two in-person ½ day sessions (8:00 am – noon), twice/year (fall & spring)
- Anticipate July 2021 start
- Include breaks and time for Q&A with instructors

Enrollment

- Online via REDCap
- Open enrollment

Day 1

Length	Topic(s)
20	**Introduction to Clinical Trials at MUSC** • MUSC research offices • Personnel • Submission procedures
20	**SCTR Services** • SUCCESS Center, SPARCRequest, RCM, Nexus • Resources
30	**Research Opportunities & Workflow Development** • Competing trials • Access to patients • Research team availability/capacity • Information needed to make a decision: protocol, sponsor, drug mechanism, CDA • Sponsor vs. IRB requirements • Pharmacy Oversight & Management • Lab Processing • Scheduling Research Visits
20	**Office of Clinical Research (OCR)/Prospective Reimbursement Analysis (PRA)** • Role of OCR • PRA overview • CTMS • eReg

40	**Budget Preparation – Corporate/Federal** • Personnel/responsibilities – how effort is determined • How to determine if a budget is practical • What is negotiable and what is not • Common pitfalls • Role of investigator sponsors • Corporate vs. Federal structural similarities and differences • ACTIVITY: Review budget and highlight what PIs need to focus on
20	**Contract Review & Execution** • ORSP role • Process/steps – including holdups and delays • Differences between Industry and Federal contracts and reviews • Master agreements
30	**IRB Application** • When to use central vs. local IRB vs. relying on other institutions (multi-site trials) • Concerns re. vulnerable populations; existence of a LAR • Audits overview • Continuing reviews

Day 2

40	**Recruitment & Community Engagement** • Importance of a recruitment plan ○ Integration of special populations/representative samples • Etiquette and policies for recruiting patients • Leveraging research preferences • Honest broker data requests • Budgeting – time and money • Recruitment tools
20	**Adverse Events/Protocol Deviations** • PI responsibilities to the sponsor and IRB • Timeliness of reporting • Protocol deviations – guidelines
40	**PI Responsibilities/Oversight** • Types of site visits – IRB, FDA, CRA • Data audits explainer • Compliance • How to address monitoring visits • Regulatory considerations – eReg, FDA Form 1572, ClinicalTrials.gov, etc. • Sponsor/CRO communications
30	**Coordinator/Staff Oversight** • Coordinator roles and responsibilities • Knowing when to hire additional staff