Good Clinical Practice at an Academic Research Institution

Day One: Thursday, May 30, 2019

Time	Speaker	Topic
2:00-2:10pm	Stacey Grabert	Welcome and Course Overview
2:10-2:30pm	Andy Nierenberg	Why is GCP Important?
2:30-3:15pm	Sarah Jordan	Privacy and Security in Clinical Research
3:15-4:15pm	Pamela Richtmyer	Introduction to Good Clinical Practice

Day Two: Thursday, June 6, 2019

Time	Speaker	Topic
2:00-2:45pm	Pearl O'Rourke	Regulatory Requirements for Human Subjects Research
2:45-3:15pm	Kirsten Resnick	The Research Protocol
3:15-3:45pm	Blair Parry	Recruitment, Remuneration and Retention
3:45-4:30pm	Elizabeth Hohmann	Process of Informed Consent

Day Three: Thursday, June 13, 2019

Time	Speaker	Topic
2:00-3:00pm	Kathy Vernovsky	Regulatory Binder, Essential Documents and RedCap
3:00-3:45pm	Elizabeth Hohmann	Unanticipated Problems Including Adverse Events
3:45-4:30pm	Priya Bowden	FDA Regulations: IND/IDE

Day Four: Thursday, June 20, 2019

Time	Speaker	Topic
2:00-2:45pm	Matthew Stafford	Special Considerations for Pediatric Studies
2:45-3:15pm	Kevin Anger	Drug Accountability: Investigational Drug Pharmacy
3:15-3:45pm	Pamela Richtmyer	Drug & Device Accountability: Site Perspective
3:45-4:30pm	Kathy Vernovsky	SOPs to Comply with GCP

Day Five: Thursday, June 27, 2019

Time	Speaker	Topic
2:00-2:30pm	Erin Elias	Study Monitoring
2:30-3:15pm	Pamela Richtmyer	Study Audits
3:15-4:00pm	Elizabeth Hohmann	Potpourri of IRB Issues
4:00-4:30pm	Emily Sobiecki	Research Misconduct Prevention

**All sessions are held in the MGH Simches Research Building, 3rd floor, room 3.110

****Note: All slides and handouts will be sent 2 days prior to each session*