BRIGHAM HEALTH

BRIGHAM AND WOMEN'S HOSPITAL

Research Education Program

Brigham & Women's Hospital

Good Clinical Practice (GCP)

at an Academic Research Institution

Wednesdays in October 2018: 3rd, 10th, 17th, and 24th
1:15PM – 4:45PM

Hale Building for Transformative Medicine
3rd Floor Conference Space

Research Education Program Manager: Chelsea Nickerson, EdM

Wednesday, October 3, 2018

1:15 – 1:30PM	Registration	
1:30 – 2:00PM	Keynote Address	**Pamela Richtmyer** Director, Partners Human Research Affairs Quality Improvement Program
2:00 – 2:45PM	Introduction to Good Clinical Practices	**Pamela Richtmyer** Director, Partners Human Research Affairs Quality Improvement Program
2:45 – 3:00PM	*Break*	
3:00 – 4:00PM	Regulatory Requirements & Human Subject Protection	**Pearl O'Rourke, MD** Director, Partners Human Research Affairs
4:00 – 4:45PM	Impact of HIPAA on Clinical Research; Privacy and Security of Subject Information	**Megan Morash** Chair, Human Research – Partners Research Management **Christina Mazzone** Information Security Officer, BWH Information Systems

Wednesday, October 10, 2018

1:15 – 1:30PM	Registration	
1:30 – 2:15PM	Essential Documents	**Daniel Jones, MSN, RN** Senior QA/QI Specialist, Partners QI Program
2:15 – 3:00PM	Study Audits	**Daniel Jones, MSN, RN** Senior QA/QI Specialist, Partners QI Program
3:00 – 3:15PM	*Break*	
3:15 – 3:45PM	Study Monitoring	**Pamela Richtmyer** Director, Partners Human Research Affairs Quality Improvement Program
3:45 – 4:45PM	Pediatric Studies	**Susan Kornetsky, MPH** BCH, Director of Clinical Research Compliance

Wednesday, October 17, 2018

1:15 – 1:30PM	Registration	
1:30 – 2:15PM	Research Compliance & Research Billing	**Kathryn Holthaus, MA, MS** Director of Research Subjects Protection and Laboratory Safety Compliance **Margaret Lyons** Research Billing Compliance Auditor
2:15 – 2:40PM	GCP & International Studies	**Barbara Bierer, MD** Faculty Director, Multi-Regional Clinical Trials Center; HMS Professor of Medicine
2:40 – 3:15PM	Unanticipated Problems Including Adverse Events	**Elizabeth Hohmann, MD** Chair, Partners IRB; HMS Associate Professor; MGH, Department of Medicine, Infectious Disease Unit
3:15 – 4:00PM	Process of Informed Consent	**Elizabeth Hohmann, MD** Chair, Partners IRB; HMS Associate Professor; MGH, Department of Medicine, Infectious Disease Unit

Wednesday, October 24, 2018

1:15 – 1:30PM	Registration	
1:30 – 2:00PM	Source Documentation & Data Collection	**Oluwanisola (Sola) Odesina, MA** QA/QI Specialist, Partners QI Program
2:00 – 2:45PM	FDA Regulations: INDs/IDEs	**Isabel Chico Calero, DVM, PhD** Senior Regulatory Specialist, Partners QI Program
2:45 – 3:15PM	Drug Accountability	**Kevin Anger, PharmD, BCPS** Pharmacy Manager, BWH Investigational Drug Services
3:15 – 3:30PM	*Break*	
3:30 – 4:15PM	Research Misconduct	**Allison Moriarty, MPH** Vice President, BWH Research Administration & Compliance
4:15 – 4:45PM	Conflict of Interest	**Christopher Clark** Legal Counsel, Office of the General Counsel **Kim Lincoln** Program Manager for Research Activities, Office for Interactions with Industry