COURSE OUTLINE: GS21 1014: Design and Management of Clinical Trials

Lectures

Introduction to Course	Dr. Aman Buzdar	1 hr
Overview Clinical Research	Dr. Jorge Cortes	1 hr
Research Ethics and the IRB	Dr. Richard Theriault	1 hr
Clinical Trial Design	Dr. Kennth Hess	2 hrs
IND or IND Exemption	Chiq Hatten	1 hr
Financial Aspects of Clinical Research	Mary Veazie	1 hr
Overview of Federal Regulations and ICH Guidelines	Chiq Hatten	2 hr
Institutional Review Boards	Wanda Quezada	2 hr
Protocol Writing	Anthea Atwell	2 hr
Informed Consent	Dr. Ty Hoover	2 hr
Adverse Events	Anthea Atwell	2 hr
Scientific Integrity	Dr. Richard Theriault	1 hr
Monitoring and Auditing Requirements	Cathy Henceroth	1 hr
Human Tissue-Based Research	Dr. Ty Hoover	1 hr
Project Management	Evanna Winston	1 hr
Job Opportunities in the Field	Dr. Linda Elting	1 hr

Assigned Reading

1. Ethical and Regulatory Aspects of Clinical Research by Ezekiel Emmanuel
2. Fundamentals of Clinical Trials, Third Edition by Lawrence M. Friedman

Practicums (2 of 3 required)

IRB Practicum
Clinical Trial Management
Research Nurse/Study Coordinator Practicum

Final Examination