

Course Outline:
GS210014 Design and Management of Clinical Trials

Lectures

Introduction to Course	Dr. Aman Buzdar	1 hr
Overview Clinical Research	Paul Papagni	1 hr
Research Ethics and the IRB	Dr. Richard Theriault	1 hr
Clinical Trial Design	Dr. Kenneth Hess	2 hrs
IND or IND Exemption	Chiq Hatten	1 hr
Economics of Medical Care & Clinical Research (Oncology Focused)	Paul Papagni	1 hr
Overview of Federal Regulations and ICH Guidelines	Chiq Hatten	2 hr
Institutional Review Boards	Wanda Queazada	2 hr
Protocol Writing	Anthea Atwell	2 hr
Informed Consent	Paul Papagni	2 hr
Adverse Events	Anthea Atwell	2 hr
Scientific Integrity	Dr. Richard Theriault	1 hr
Monitoring and Auditing Requirements	Cathy Henceroth	1 hr
Project Management	Martha Matza	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
Compliance Office
Research Nurses/Study Coordinators

Project Report for each practicum

Final Examination