

# NIH Introduction to the Principles and Practice of Clinical Research Course

## 2020-2021 Syllabus

Module 1: Introduction to Clinical Research	
Lecture	Presenter
History of Clinical Research	Dr. John I. Gallin
Ethical Principles in Clinical Research	Dr. Christine Grady
Research Ethics	Dr. Ezekiel Emanuel
Legal Issues in Clinical Research	Carrie Kennedy, JD
FDA Product Regulation	Dr. Chris Joneckis
Module 2: Conceptualizing the Clinical Trial	
Session	Presenter
Introduction to Clinical Study Design	Dr. Laura Lee Johnson
Informational Resources for Clinical Research	Mr. Josh Duberman
Choosing a Research Question	Dr. John Powers, III
Overview of Hypothesis Testing	Dr. Paul Wakim
Sample Size and Power	Dr. Laura Lee Johnson
Issues in Randomization	Dr. Paul Wakim
Measures	Dr. David Luckenbaugh
Quality of Life	Dr. Kevin Weinfurt
Study Participant Selection	Dr. Catherine Stoney
Considering Inclusion in Research	Dr. Janine Austin Clayton
Health Disparities Research	Dr. Larissa Aviles-Santa
Research with Vulnerable Participants	Dr. David Wendler
Using Large Datasets for Population-Based Health Research	Dr. Leighton Chan
Module 3: Writing the Protocol & Protocol Implementation	
Session	Presenter
Developing Protocols and Manuals of Operating Procedures	Dr. Wendy Weber
Evaluation of a Protocol Budget	Dr. Phyllis Klein
Technology Transfer	Dr. Bruce Goldstein
Clinical Data Interchange Standards (CDISC)	Dr. Stephen Wilson
Module 4: Safety Review & Monitoring	
Session	Presenter
Institutional Review Boards	Dr. Jerry Menikoff
Mock IRB	Dr. Jerry Menikoff
Data and Safety Monitoring Committees	Dr. Pamela Shaw
Module 5: Data Quality & Results Reporting	
Session	Presenter
Research Misconduct: Fabrication, Falsification, & Plagiarism	Dr. James Gulley
Quality Management in Clinical Research	Dr. Liz Ness
Data Management & Case Report Form Development	Dr. Marge Good
Clinical Trials Registration & Results Reporting	Dr. Deborah Zarin

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Module 6: Topics of Special Interest	
Session	Presenter
Secondary Data/Meta-Analysis	Dr. Charles Natanson
Conceptual Approach to Survival Analysis	Dr. Laura Lee Johnson
Dissemination and Implementation Research	Dr. Catherine Stoney
Designing and Testing Questionnaires	Ms. Barbara Stussman
Pharmaceutical Development: Management of Projects	Dr. Christopher Breder
NIH Peer Review Process	Dr. Valerie Prenger
Community – Based Participatory Research	Dr. Tiffany M. Powell-Wiley
The Clinical Researcher and the Media	Mr. John Burklow