NIH Introduction to the Principles and Practice of Clinical Research Course
2024-2025

Module 1: Introduction to Clinical Research		
	Session	**Presenter**
1	History of Clinical Research	Dr. John I. Gallin
2	Clinical Research Overview/Roadmap	Dr. Anne Zajicek & Dr. Lisa Cordes
3	Clinical Research Team	Various Speakers
4	Good Clinical Practice and Good Manufacturing Practice in Clinical Research	Alissa Mun and Rachel Evans
5	FDA Product Regulation	Dr. Chris Joneckis
6	Overview of the European Medicines Agency (EMA)	Dr. Anabela Marcal
7	Ethical Principles in Clinical Research ***UPDATED***	Dr. Christine Grady
8	Research Ethics	Dr. Ezekiel Emanuel
9	Legal Issues in Clinical Research	Carrie Kennedy, JD

Module 2: Conceptualizing the Clinical Trial Study/Protocol		
	Session	**Presenter**
1	Introduction to Clinical Study Design	Dr. Laura Lee Johnson
2	Choosing a Research Question	Dr. John Powers, III
3	Designing Trials Efficiently	Dr. John Powers, III
4	A Clinical Perspective on Clinical Research Endpoints	Dr. Daniel Benjamin
5	Overview of Hypothesis Testing	Dr. Paul Wakim
6	Choosing a Study Design	Dr. Daniel Benjamin
7	Sample Size and Power	Dr. Laura Lee Johnson
8	Issues in Randomization	Dr. Paul Wakim
9	Measures	Dr. David Luckenbaugh
10	Quality of Life	Dr. Kevin Weinfurt
11	Information Resources for Clinical Research	Tracy Shields

Module 3: Inclusion and Selection of Study Participants		
	Session	**Presenter**
1	Community Engagement and Community-Based Participatory Research	Dr. Tiffany M. Powell-Wiley
2	Considering Inclusion in Research	Dr. Janine Austin Clayton, Dawn Corbett & Dr. Samia Noursi
3	Health Disparities Research	Dr. Larissa Aviles-Santa
4	Research with Vulnerable Participants	Dr. David Wendler
5	Study Participant Selection	Dr. Catherine Stoney
6	Health Research Linked to Disasters and Other Humanitarian Crises	Dr. Larissa Aviles-Santa

NIH Introduction to the Principles and Practice of Clinical Research Course
2024-2025

Module 4: Writing the Protocol & Protocol Implementation		
	Session	**Presenter**
1	Introduction to Writing a Protocol	Dr. Anne Zajicek & Dr. Lisa Cordes
2	Dose Selection for Investigational Agents: Moving from Pre-clinical Models into First-In-Human Dosing	Dr. Jerry Collins
3	Developing Protocols and Manuals of Operating Procedures	Dr. Wendy Weber
4	Development of a Protocol Budget	Dr. Phyllis Klein
5	NIH Peer Review Process	Dr. Nicholas Gaiano
6	Technology Transfer	Dr. Bruce Goldstein
7	Common Data Elements	Dr. Jon McKeeby

Module 5: Safety Review & Monitoring		
	Session	**Presenter**
1	Adverse Events Reporting	Elizabeth Ness
2	Institutional Review Boards - Overview	Dr. Jerry Menikoff
3	Mock IRB	Dr. Jerry Menikoff
4	Data and Safety Monitoring Committees	Dr. Pamela Shaw

Module 6: Data Quality & Results Reporting		
	Session	**Presenter**
1	Research Misconduct: Fabrication, Falsification, & Plagiarism	Dr. James Gulley
2	Quality Management in Clinical Research	Elizabeth Ness
3	Data Management Overview	Christine Gordon
4	Data Collection & Case Report Form Development	Dr. Marge Good
5	Clinical Data Interchange Standards (CDISC)	Dr. Jon McKeeby
6	Clinical Trials Registration & Results Reporting & Data Sharing	Dr. Stacey Arnold
Topics of Special Interest		
	Session	**Presenter**
1	Secondary Data/Meta-Analysis	Dr. Charles Natanson
2	Conceptual Approach to Survival Analysis	Dr. Laura Lee Johnson
3	Dissemination and Implementation Research	Dr. Catherine Stoney
4	Designing and Testing Questionnaires	Barbara Stussman
5	Pharmaceutical Development: Management of Projects	Dr. Christopher Breder
7	The Clinical Researcher and the Media	John Burklow
8	Using Large Datasets for Population-Based Health Research	Dr. Leighton Chan