

**NIH Introduction to the Principles and Practice of Clinical Research Course
2022-2023**

Module 1: Introduction to Clinical Research		
	Session	Presenter
1	History of Clinical Research	Dr. John I. Gallin
2	Clinical Research Overview *NEW*	Dr. Anne Zajicek & Dr. Lisa Cordes
3	Clinical Research Team *NEW*	Various Speakers
4	FDA Product Regulation	Dr. Chris Joneckis
5	Ethical Principles in Clinical Research	Dr. Christine Grady
6	Research Ethics	Dr. Ezekiel Emanuel
7	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	Information Resources for Clinical Research	Mr. Josh Duberman
3	Choosing a Research Question	Dr. John Powers, III
4	Designing Trials Efficiently	Dr. John Powers, III
5	Overview of Hypothesis Testing	Dr. Paul Wakim
6	Sample Size and Power	Dr. Laura Lee Johnson
7	Issues in Randomization	Dr. Paul Wakim
8	Measures	Dr. David Luckenbaugh
9	Quality of Life	Dr. Kevin Weinfurt
10	Study Participant Selection	Dr. Catherine Stoney
11	Considering Inclusion in Research	Dr. Janine Austin Clayton, Dawn Corbett & Dr. Samia Noursi
12	Health Disparities Research	Dr. Larissa Aviles-Santa
13	Research with Vulnerable Participants	Dr. David Wendler
14	Health Research Linked to Disasters and Other Humanitarian Crises	Dr. Larissa Aviles-Santa

Module 3: Protocol Review, Implementation & Monitoring		
	Session	Presenter
1	Developing Protocols and Manuals of Operating Procedures	Dr. Wendy Weber
2	NIH Peer Review Process *NEW*	To Be Determined
3	Technology Transfer	Dr. Bruce Goldstein
4	Institutional Review Boards - Overview	Dr. Jerry Menikoff
5	Mock IRB	Dr. Jerry Menikoff
6	Data and Safety Monitoring Committees	Dr. Pamela Shaw

Module 4: Data Quality & Results Reporting		
	Session	Presenter
1	Research Misconduct: Fabrication, Falsification, & Plagiarism	Dr. James Gulley
2	Quality Management in Clinical Research	Elizabeth Ness, MS, BSN
3	Data Management & Case Report Form Development	Dr. Marge Good
4	Clinical Data Interchange Standards (CDISC)	Dr. Stephen Wilson
5	Clinical Trials Registration & Results Reporting *NEW*	To Be Determined

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Module 5: 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	Ms. Barbara Stussman
5	Pharmaceutical Development: Management of Projects	Dr. Christopher Breder
6	Community – Based Participatory Research	Dr. Tiffany M. Powell-Wiley
7	The Clinical Researcher and the Media	Mr. John Burklow
8	Using Large Datasets for Population-Based Health Research	Dr. Leighton Chan