

**Introduction to the Principles and Practice of Clinical Research Course
2026-2027**

Module 1: Introduction to Clinical Research		
	Session	Presenter
1	History of Clinical Research	Dr. John I. Gallin
2	Good Clinical Practice and Good Manufacturing Practice in Clinical Research	Alissa Mun and Rachel Evans
3	FDA Product Regulation	Dr. Chris Joneckis
4	The European Union Regulatory Framework for Medicines	Dr. Anabela Marcal
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: Statistics in Clinical Research		
	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	Overview of Hypothesis Testing	Dr. Paul Wakim
5	Sample Size and Power	Dr. Laura Lee Johnson
6	Issues in Randomization	Dr. Paul Wakim
7	Measures	Dr. David Luckenbaugh
8	Quality of Life	Dr. Kevin Weinfurt

Module 3: Practical Considerations for Implementation		
	Session	Presenter
1	Clinical Research Team	Various Speakers
2	Choosing a Study Design	Dr. Daniel Benjamin
3	A Clinical Perspective on Clinical Research Endpoints	Dr. Daniel Benjamin
4	Information Resources for Clinical Research	Tracy Shields

Module 4: Selection of Study Participants		
	Session	Presenter
1	Community Engagement and Community-Based Participatory Research	Dr. Tiffany M. Powell-Wiley
2	Health Disparities Research	Dr. Larissa Aviles-Santa
3	Research with Vulnerable Participants	Dr. David Wendler
4	Study Participant Selection	Dr. Catherine Stoney
5	Health Research Linked to Disasters and Other Humanitarian Crises	Dr. Larissa Aviles-Santa

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Module 5: Writing the Protocol & Protocol Implementation		
	Session	Presenter
1	Introduction to Writing a Protocol	Dr. Anne Zajicek & Dr. Lisa Cordes
2	Developing Protocols and Manuals of Operating Procedures	Dr. Wendy Weber
3	Development of a Protocol Budget	Dr. Phyllis Klein
4	Technology Transfer	Dr. Bruce Goldstein
5	Common Data Elements	Dr. Jon McKeeby

Module 6: 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 7: 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 Trials Registration & Results Reporting & Data Sharing	Dr. Stacey Arnold

Topics of Special Interest (Supplementary Materials)		
	Session	Presenter
1	Dose Selection for Investigational Agents: Moving from Pre-clinical Models into First-In-Human Dosing	Dr. Jerry Collins
2	Secondary Data/Meta-Analysis	Dr. Charles Natanson
3	Conceptual Approach to Survival Analysis	Dr. Laura Lee Johnson
4	Dissemination and Implementation Research	Dr. Catherine Stoney
5	Designing and Testing Questionnaires	Barbara Stussman
6	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
9	Clinical Data Interchange Standards (CDISC)	Dr. Jon McKeeby
10	The European Union Regulatory Framework: Supplemental Information	Dr. Anabela Marcal