**Introduction to the Principles and Practice of Clinical Research Course**
**2025-2026**

| Module 1: Introduction to Clinical Research | | |
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| | **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 | | |
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| | **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 | | |
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| | **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 | | |
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| | **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 | | |
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| | **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 | | |
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| | **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 | | |
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| | **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) | | |
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| | **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 |