NIH Introduction to the Principles and Practice of Clinical Research
2018-2019 Course Syllabus

Module 0: Introduction	
Session	**Presenter**
Welcome and a History of Clinical Research: A Merging of Diverse Cultures	Dr. John I. Gallin

Module 1: Study Design, Measurement, and Statistics	
Session	**Presenter**
Choosing a Research Question and Implications for Efficient Clinical Trials	Dr. John Powers, III
Overview of Clinical Study Design	Dr. Laura Lee Johnson
Design of Epidemiologic Studies	Dr. Laura Lee Johnson
Clinical Research from the Patient's Perspective and Study Participant Selection	Mr. Jerry Sachs and Dr. Catherine Stoney
Issues in Randomization	Dr. Paul Wakim
Overview of Hypothesis Testing	Dr. Paul Wakim
Sample Size and Power	Dr. Laura Lee Johnson
Conceptual Approach to Survival Analysis	Dr. Laura Lee Johnson
Measures	Dr. David Luckenbaugh
Quality of Life	Dr. Kevin Weinfurt
Designing and Testing Questionnaires	Ms. Barbara Stussman
Using Large Datasets for Population-Based Health Research	Dr. Leighton Chan
Secondary Data/Meta-Analysis	Dr. Charles Natanson
Module 1 Summary and Study Examples	Dr. Laura Lee Johnson

Module 2: Ethical, Legal, Monitoring, and Regulatory Considerations	
Session	**Presenter**
Legal Issues in Clinical Research	Mrs. Carrie Kennedy
Ethical Principles in Clinical Research	Dr. Christine Grady
Data and Safety Monitoring Committees	Dr. Pamela Shaw
Institutional Review Boards	Dr. Jerry Menikoff
Mock IRB	Dr. Jerry Menikoff
Research with Vulnerable Participants	Dr. David Wendler

Module 3: Preparing and Implementing Clinical Studies	
Session	**Presenter**
Developing Protocols and Manuals of Operating Procedures	Dr. Wendy Weber
Evaluation of a Protocol Budget	Ms. Phyllis Klein
Scientific Conduct	Dr. James Gulley
Inclusion of Women and Minorities in Clinical Trials	Dr. Janine Austin Clayton and Dr. Meredith D. Temple-O'Connor
Pharmaceutical Development: Management of Projects	Dr. Christopher Breder
NIH Peer Review Process	Dr. Valerie Prenger
FDA Product Regulation	Dr. Chris Joneckis

Data Management & Case Report Form Development in Clinical Trials	Ms. Marge Good
Electronic Health Records and Clinical Data Interchange Standards	Dr. Stephen Wilson
Quality Measurement in Clinical Research	Ms. Elizabeth Ness
Clinical Trial Registration and Results Reporting	Dr. Deborah Zarin
Information Resources for Clinical Research	Mr. Josh Duberman

Module 4: Additional Study Designs and Miscellaneous Topics	
Session	**Presenter**
Technology Transfer	Mr. Bruce Goldstein
Dissemination and Implementation Research	Dr. Catherine Stoney
Health Disparities Research	Dr. Larissa Aviles- Santa
Health Disparities and Community- Based Participatory Research	Dr. Tiffany M. Powell-Wiley
The Clinical Researcher and the Media	Mr. John Burklow