Introduction to the Principles and Practice of Clinical Research (IPPCR)

October 14, 2014 – March 9, 2015

All sessions will meet at 5:00 p.m. (Eastern Time) in the Lipsett Amphitheater.

Introduction	
Tuesday, October 14, 2014	Welcome (30 minutes) John I. Gallin, M.D. Director NIH Clinical Center
	History of Clinical Research: A Merging of Diverse Cultures (30 minutes) John I. Gallin, M.D. Director NIH Clinical Center **Chapter: 1**
Module I: Study Design and Statistics	
Monday, October 20, 2014 Session 1	**Unit 1:** Choosing a Research Question and Implications for Efficient Clinical Trials (90 minutes) John Powers, III, M.D. Senior Medical Scientist, NCI Frederick **Chapter: 19, 25, 29**
Tuesday, October 21, 2014 Session 2	**Unit 2:** Clinical Research from the Patient's Perspective (30 minutes) Jerry Sachs Manager of Guest Services (Retired) Smithsonian Museum of Natural History **Chapter: 17** **Unit 3:** Study Participant Selection (60 minutes) Catherine Stoney, Ph.D. Program Director Prevention and Population Sciences Program, NHLBI **Chapter: 2, 13, 19, 26; Please review archived video on** Inclusion of Women and Minorities in Clinical Trials (60 minutes) by Miriam Kelty, Ph.D. **prior to this lecture**

Monday, October 27, 2014 Session 3	**Unit 4:** Overview of Clinical Study Design (90 minutes) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM **Chapter: 19**
Tuesday, October 28, 2014 Session 4	**Unit 5:** Measures (60 minutes) David Luckenbaugh, Ph.D. Biostatistician Experimental Therapeutics and Pathophysiology Branch, NIMH **Chapter: 25, 26**
Monday, November 3, 2014 Session 5	**Unit 6:** Design of Epidemiologic Studies (90 minutes) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM **Chapter: 18**
Tuesday, November 4, 2014 Session 6	**Unit 7:** Issues in Randomization (90 minutes) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM **Chapter: 20, 24**
Thursday, November 6, 2014 Breakout Session	Breakout Session (60 minutes) Title – TBD Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM ***Session will be held in FAES Classroom #5 (B1C210)**
Monday, November 10, 2014 Session 7	**Unit 8:** Using Large Datasets for Population-Based Health Research (60 minutes) Leighton Chan, M.D. Chief, Rehabilitation Medicine Department, CC **Chapter: 28**
Tuesday, November 11, 2014 FEDERAL HOLIDAY Veterans Day	NO LECTURE

Monday, November 17, 2014 Session 8	**Unit 9:** Overview of Hypothesis Testing (90 minutes) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM **Chapter: 21, 24**
Tuesday, November 18, 2014 Session 9	**Unit 10:** Sample Size and Power (90 minutes) Laura Lee Johnson, Ph.D. , Statistician Office of Clinical and Regulatory Affairs, NCCAM **Chapter: 22, 24**
Thursday, November 20, 2014 Breakout Session	Breakout Session (60 minutes) Title – TBD Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM ***Session will be held in FAES Classroom #5 (B1C210)**
Monday, November 24, 2014 and Tuesday, November 25, 2014 Recess	**Week of Thanksgiving**-NO SCHEDULED LECTURES; MAKE-UP LECTURES AS NEEDED
Monday, December 1, 2014 Session 10	**Unit 11**: Designing and Testing Questionnaires (60 minutes) Gordon Willis, Ph.D. Cognitive Psychologist Applied Research Program, NCI **Chapter: 25**
Tuesday, December 2, 2014 Session 11	**Unit 12:** Conceptual Approach to Survival Analysis (90 minutes) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM **Chapter: 23, 24**
Thursday, December 4, 2014 Breakout Session	Breakout Session (60 minutes) Title – TBD Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM

	***Session will be held in FAES Classroom #5 (B1C210)**
Monday, December 8, 2014 Session 12	**Unit 13:** Secondary Data/Meta-Analysis (90 minutes) Charles Natanson, M.D. Senior Investigator and Head Anesthesia Section Critical Care Medicine Department, CC **Chapter: 27**
Tuesday, December 9, 2014 Session 13	**Unit 14:** Module I Summary and Study Examples (90 minutes) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM **Chapter:**
Module II: Ethical, Legal, and Regulatory Considerations	
Monday, December 15, 2014 Session 14	**Unit 1:** Ethical Principles in Clinical Research (60 minutes) Christine Grady, R.N., Ph.D. Head, Section on Human Subjects Research Chief, Bioethics Department, CC **Chapter: 2**
Tuesday, December 16, 2014 Session 15	**Unit 2:** FDA Product Regulation (60 minutes) Chris Joneckis, Ph.D. Immediate Office of the Center Director Associate Director for Review Management (Acting) Center for Biologics Evaluation Research, FDA **Chapter: 7**
Monday, December 22, 2014 through Tuesday, December 30, 2014 Recess	**Holiday Recess-**NO LECTURES
Monday, January 5, 2015 Session 16	**Unit 3:** Institutional Review Boards (90 Minutes) Jerry Menikoff, M.D., J.D. Director, Office for Human Research Protections

	Office of Public Health and Science, DHHS **Chapter: 5, 6**
Tuesday, January 6, 2015 Session 17	**Unit 4: Mock IRB (120 minutes)** Jerry Menikoff, M.D., J.D. Director, Office for Human Research Protections Office of Public Health and Science, DHHS **Chapter: 5, 6**
Monday, January 12, 2015 Session 18	**Unit 5**: Research with Vulnerable Participants (60 minutes) David Wendler, Ph.D. Head, Unit on Vulnerable Populations Section on Human Subjects Research, Bioethics Department, CC **Chapter: 2, 5**
Module III: Preparing and Monitoring Clinical Studies	
Tuesday, January 13, 2015 Session 19	**Unit 1:** Information Resources for Clinical Research (90 minutes) Josh Duberman, M.L.I.S. Informationist/Research Librarian, NIH Library **Chapter:**
Monday, January 19, 2015 FEDERAL HOLIDAY Martin Luther King Day	NO LECTURE
Tuesday, January 20, 2015 Session 20	**Unit 2:** Protocol Development (60 minutes) Wendy Weber, N.D., Ph.D., M.P.H. Program Officer Division of Extramural Research, NCCAM **Chapter: 29, 32** **Unit 3:** Protocol Mechanics and Tools (30 minutes) Philip Lightfoot, B.S., B.A. Systems Analysis Department of Clinical Research Informatics, CC

	Chapter: 32
Monday, January 26, 2015 Session 21	**Unit 4:** Pharmaceutical Development: Management of Projects (60 minutes) **Speaker T.B.D.** **Chapter: 7, 26, 37, 43**
Tuesday, January 27, 2015 Session 22	**Unit 5:** Evaluation of a Protocol Budget (90 minutes) Phyllis Klein, R.N., CCRC, BSN Director, Regulatory Support and Compliance Washington University in St. Louis **Chapter: 33; prior to the lecture review archived video on** Development of Manuals of Operating Procedures (90 minutes) by Wendy Weber, N.D., Ph.D., M.P.H.
Monday, February 2, 2015 Session 23	**Unit 6:** NIH Peer Review Process (90 minutes) Valerie Prenger, Ph.D., M.H.S. Director Office of Scientific Review, NHLBI **Chapter: 36**
Tuesday, February 3, 2015 Session 24	**Unit 7:** Design of Case Report Forms (30 minutes) Diane St. Germain, R.N., M.S., C.R.N.P. Nurse Consultant Division of Cancer Prevention, NCI **Chapter: 33, 37** **Unit 8:** Data Management in Clinical Trials (30 minutes) Diane St. Germain, R.N., M.S., C.R.N.P. Nurse Consultant Division of Cancer Prevention, NCI **Chapter: 8**
Monday, February 9, 2015 Session 25	**Unit 9:** Basic Data Representation (60 minutes) Jim Cimino, M.D. Chief

	Laboratory for Informatics Development, CC **Chapter:**
Tuesday, February 10, 2015 Session 26	**Unit 10:** Data & Non-Data Aspects of Quality Control in Clinical Studies (60 minutes) Elizabeth Ness, R.N., MSN Staff Development NCI/CCR **Chapter:**
Monday, February 16, 2015 FEDERAL HOLIDAY President's Day	NO LECTURE
Tuesday, February 17, 2015 Session 27	**Unit 11:** Data and Safety Monitoring Committees (90 minutes) Pamela Shaw, Ph.D. Assistant Professor Department of Biostatistics and Epidemiology Perelman School of Medicine University of Pennsylvania **Chapter: 9**
Monday, February 23, 2015 Session 28	**Unit 12:** Clinical Trial Registration and Results Reporting (90 minutes) Deborah Zarin, M.D. Assistant Director for Clinical Research Projects Lister Hill National Medical Center for Biomedical Communications, NIH **Chapter: 15**
Module IV: Miscellaneous Topics	
Tuesday, February 24, 2015 Session 29	**Unit 1:** Technology Transfer (90 minutes) Bruce Goldstein, J.D. Unit Coordinator Technology Transfer Branch, NCI **Chapter: 30, 31**

Monday, March 2, 2015 Session 30	**Unit 2:** Scientific Conduct (60 minutes) James L. Gulley, M.D., Ph.D., F.A.C.P. Director Clinical Trials Group, Center for Cancer Research, NCI **Chapter: 4, 12**
Tuesday, March 3, 2015 Session 31	**Unit 3:** Health Disparities Research (60 minutes) Larissa Avilés-Santa, M.D., M.P.H., F.A.C.P., F.A.C.E. Division of Cardiovascular Sciences, NHLBI **Chapter: 46**
Monday, March 9, 2015 Session 32	**Unit 4:** Community-Based Participatory Research (30 minutes) Francisco Sy, M.D., Dr PH Director Division of Extramural Activities and Science Programs, NIMHD **Chapter: 46** **Unit 5:** Dissemination and Implementation Research (60 minutes) Catherine Stoney, Ph.D. Program Director Prevention and Population Sciences Program, NHLBI **Chapter:**

Lectures to be Viewed on Archives	
Please view lecture prior to Dr. Catherine Stoney's October 21, 2014 lecture: "Study Participant Selection"	**Inclusion of Women and Minorities in Clinical Trials** (60 minutes) Miriam Kelty, Ph.D. Special Volunteer Former Associate Director, Extramural Activities, NIA **Chapter: 13**
Please view lecture prior to Dr. Laura Lee Johnson's December 2, 2014 lecture: "Conceptual Approach to	**Quality of Life** (45 minutes) John Ware, Ph.D. Chief Science Officer

Survival Analysis”	John Ware Research Group, Inc. **Chapter: 25**
	The Clinical Researcher and the Media (45 minutes) John Burklow, M.S. Associate Director for Communications Office of Communications and Public Liaison, NIH **Chapter: 16**
	Legal Issues in Clinical Research (60 minutes) Carrie Pottker-Fishel, J.D. Attorney Advisor Office of General Counsel, NIH **Chapter: 11**
Please view lecture after Wendy Weber’s January 20, 2015 lecture: “Protocol Development” and prior to Phyllis Klein’s January 27, 2015 lecture: “Evaluation of a Protocol Budget”	**Development of Manuals of Operating Procedures** (90 minutes) Wendy Weber, N.D., Ph.D., M.P.H. Program Director Division of Extramural Research, NCCAM **Chapter: 29**