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

October 27, 2008 – March 17, 2009

All sessions will meet on Monday and Tuesday evenings from 5:00 p.m. to approximately 6:30 p.m. (Eastern Standard Time) in the Lipsett Amphitheater.

Introduction	
Monday, October 27th Session 1	Welcome (30 minutes) John I. Gallin, M.D. Director, NIH Clinical Center
	Unit 1: History of Clinical Research and Choosing a Research Question (30 minutes) John I. Gallin, M.D. Director, NIH Clinical Center
Module I, Statistical Methods	
Tuesday, October 28th Session 2	Unit 2: Participant Selection (45 minutes) Tamara Harris, M.D., M.S. Chief, Geriatric Epidemiology Section, NIA
	Unit 3: Using Secondary Data and Meta Analysis (45 minutes) Tamara Harris, M.D., M.S. Chief, Geriatric Epidemiology Section, NIA
Monday, November 3rd Session 3	Unit 4: Design of Epidemiologic Studies (1.5 hours) Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Tuesday, November 4th Session 4	Unit 5: Measures (1 hour) David Black, Ph.D. Psychologist Pediatric and Development Neuropsychiatry, NIMH Affairs, NCCAM
Monday, November 10th Session 5	Unit 6: Economic Analysis in Clinical Research (1.5 hours) Martin Brown, Ph.D. Chief, Health Services and Economics Branch, NCI
Tuesday, November 11th	FEDERAL HOLIDAY
Monday, November 17th Session 6	Unit 7: Study Development (1.5 hours) Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory
Tuesday, November 18th Session 7	Unit 8: Issues in Randomization (1.5 hours) Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Thursday, November 20th Session 8	Breakout Session – (1 hour) Title – TBD Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Monday, November 24th	RECESS
Tuesday, November 25th	RECESS

Monday, December 1st Session 9	Unit 9: Overview of Hypothesis Testing (1.5 hours) Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Tuesday, December 2nd Session 10	Unit 10: Sample Size and Power (1.5 hours) Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Thursday, December 4th Session 11	Breakout Session – (1 hour) Title – TBD Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Monday, December 8th Session 12	Unit 11: Conceptual Approach to Survival Analysis (1.5 hours) Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Tuesday, December 9th Session 13	Unit 12: Designing and Testing Questionnaires (1 hour) Jack Guralnik, M.D., Ph.D. Chief, Epidemiology and Demography Section, NIA
Thursday, December 11th Session 14	Breakout Session – (1 hour) Title – TBD Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Monday, December 15th Session 15	Unit 13: Opportunities for Innovation in Clinical Research: From Molecule to Medicare - Part I (45 minutes) Mitchell Max, M.D. Director, Molecular Epidemiology of Pain Program Professor of Anesthesiology, Medicine, and Human Genetics University of Pittsburgh
	Unit 14: Opportunities for Innovation in Clinical Research: From Molecule to Medicare - Part II (45 minutes) Joanne Lynn, M.D. Medical Officer Office of Clinical Standards and Quality Centers for Medicare and Medicaid Services, HHS
Module II, Ethical Issues and Regulation of Human Subjects Research	
Tuesday, December 16th Session 16	Unit 1: Researching an Ethics Question (45 minutes) Ezekiel Emanuel, M.D., Ph.D. Chief, Bioethics Department, CC
	Unit 2: Ethical Principles in Clinical Research (45 minutes) Christine Grady, R.N., Ph.D. Head, Section on Human Subjects Research Bioethics Department, CC
Monday, December 22nd	RECESS
Tuesday, December 23rd	RECESS
Monday, December 29th	RECESS
Tuesday, December 30th	RECESS

Monday, January 5th Session 17	Unit 3: Legal Issues in Clinical Research (1 hour) Valerie Bonham, J.D. Senior Attorney Office of General Counsel, NIH
	Unit 4: Concepts in the Management of Projects (1 hour) Charles Grudzinskas, Ph.D. Principal, NDA Partners LLC and Adjunct Professor Georgetown University Medical Center Due to unforeseen circumstances this lecture will not take place at this time; however, it may be rescheduled at a later date. The handout and the video file will be posted to the course website.
Tuesday, January 6th Session 18	**Breakout Session:** Mock IRB (2 hours) TBD Health Science Policy Analyst Office of Human Subjects Research, NIH
Monday, January 12th Session 19	Unit 5: Evaluation of a Protocol Budget (1.5 hours) Margaret Matula, R.N., B.S.N., M.G.A. Director, Research and Clinical Trials Anne Arundel Medical Center
Tuesday, January 13th Session 20	Unit 6: Special Lecture: Human Genome Project and Clinical Research (1 hour) Christopher Austin, M.D. Senior Translation Research Advisor to the Director, NHGRI
Monday, January 19th	FEDERAL HOLIDAY
Tuesday, January 20th	FEDERAL HOLIDAY
Thursday, January 22 Session 21	**Breakout Session:** Legal Issues in Clinical Research (1 hour) Patricia Kvochak, J.D. Deputy NIH Legal Advisor, NIH
Module III, Monitoring Patient-Oriented Research and Regulatory Issues	
Monday, January 26th Session 22	Unit 1: FDA Product Regulation (1.25 hours) Robert Yetter, Ph.D. Associate Director for Review Management Center for Biologics Evaluation and Research, FDA
Tuesday, January 27th Session 23	Unit 2: The Clinical Researcher and the Media (45 minutes) John Burklow, M.S. Associate Director for Communications Office of Communications and Public Liaison, NIH
	Unit 3: Product Development: Moving from the Bench to the Clinic (45 minutes) Richard Schwartz, Ph.D. Chief, Vaccine Production Program Lab Vaccine Research Center/NIAID/NIH
Monday, February 2nd	Unit 4: Data and Safety Monitoring Boards (1 hour)

Session 24	Dennis O. Dixon, Ph.D. Mathematical Statistician Biostatistics Research Branch, NIAID
Tuesday, February 3rd Session 25	Unit 5: Data Management in Clinical Trials (1 hour) Diane St. Germain, R.N., M.S., C.R.N.P. Nurse Consultant Division of Cancer Prevention, NCI
Monday, February 9th Session 26	Unit 6: Quality Control in Clinical Trials (1 hour) Jack Guralnik, M.D., Ph.D. Chief, Epidemiology and Demography Section, NIA
Tuesday, February 10th Session 27	Unit 7: Quality of Life (1 hour) John Ware, Ph.D. CEO and Chief Science Officer, QualityMetric, Inc
Module lV, Preparing and Funding a Clinical Research Study	
Monday, February 16th	FEDERAL HOLIDAY
Tuesday, February 17th Session 28	Unit 1: Scientific Conduct (45 minutes) Joan Schwartz, Ph.D. Assistant Director Office of Intramural Research, NIH
Monday, February 23rd Session 29	Unit 2: ProtoType and Protocol Mechanics (1 hour) Philip Lightfoot, B.S., B.A. Systems Analysis, DCRI, CC
Tuesday, February 24th Session 30	Unit 3: Information Resources for Clinical Research (1 hour) Josh Duberman, M.L.I.S. Informationist/Research Librarian
Monday, March 2nd Session 31	Unit 4: Clinical Research from the Patient's Perspective (1 hour) Susan Butler, B.A., M.A. Vice President, Ovarian Cancer National Alliance
Tuesday, March 3rd Session 32	Unit 5: Design of Case Report Forms (1 hour) David Mailhot, B.S., M.P.H. Director, Global Research and Development Global Clinical Data Services Pfizer Global Research and Development
Monday, March 9th Session 33	Unit 6: NIH Peer Review Process (1 hour) Olivia Bartlett, Ph.D. Chief, Research Programs Review, NCI
Tuesday, March 10th Session 34	Unit 7: Technology Transfer (1.5 hours) Bruce Goldstein, J.D. Unit Coordinator, Technology Transfer Branch, NCI
Monday, March 16th Session 35	Unit 8: Inclusion of Women and Minorities in Clinical Trials (1 hour) Miriam Kelty, Ph.D. Former Associate Director, Extramural Activities, NIA
Tuesday, March 17th Session 36	Unit 9: Evaluation of Alternative and Complementary Therapies (1 hour) Marc Blackman, M.D.

	Associate Chief of Staff for Research and Development Veteran's Administration Medical Center

*Schedule subject to change