

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

October 19, 2009 – March 15, 2010

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 19 th Session 1	Welcome (30 minutes) John I. Gallin, M.D. Director, NIH Clinical Center
	Unit 1: History of Clinical Research: A Merging of Diverse Cultures (30 minutes) John I. Gallin, M.D. Director, NIH Clinical Center
Module I, Statistical Methods	
Tuesday, October 20 th 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, October 26 th 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, October 27 th Session 4	Unit 5: Measures (1 hour) David Black, Ph.D. Psychologist Pediatric and Development Neuropsychiatry, NIMH Affairs, NCCAM
Monday, November 2 nd Session 5	Unit 6: Designing and Testing Questionnaires Jack Guralnik, M.D., Ph.D. Chief, Epidemiology and Demography Section, NIA
Tuesday, November 3 rd Session 6	Unit 7: Economic Analysis in Clinical Research (1.5 hours) NO lecture today. The 2008 video is on the course website.
Thursday, November 5 th Session 7	Breakout Session – (1 hour) Title – TBD Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Monday, November 9 th Session 8	Unit 8: Issues in Randomization (1.5 hours) Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Tuesday, November 10 th Session 9	Unit 9: Overview of Hypothesis Testing (1.5 hours) Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Thursday, November 12 th Session 10	Breakout Session – (1 hour) Title – TBD Laura Lee Johnson, Ph.D.

	Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Monday, November 16 th Session 11	Unit 10: Sample Size and Power (1.5 hours) Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Monday, November 17 th 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
Thursday, November 19 th Session 13	Breakout Session – (1 hour) Title – TBD Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Monday, November 23 rd	RECESS
Tuesday, November 24 th	RECESS
Tuesday, November 30 th Session 14	Unit 12: Ethical Principles in Clinical Research (45 minutes) Christine Grady, R.N., Ph.D. Head, Section on Human Subjects Research Bioethics Department, CC
	Unit 13: Research with Vulnerable Participants (45 minutes) David Wendler, Ph.D. Head, Unit on Vulnerable Populations Section on Human Subjects Research, Clinical Bioethics Department, CC
Tuesday, December 1 st Session 15	Unit 14: Efficient Clinical Trials Dr. John Powers, III, M.D. Senior Medical Scientist, NCI-Frederick
Monday, December 7 th Session 16	Unit 15: Study Development (1.5 hours) Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory
Module II, Ethical Issues and Regulation of Human Subjects Research	
Tuesday, December 8 th Session 17	Unit 1: Legal Issues in Clinical Research (1 hour) Valerie Bonham, J.D. Senior Attorney, Office of General Counsel, NIH
Monday, December 14 th Session 18	Unit 2: Concepts in the Management of Projects (1 hour) Christopher Breder, M.D., Ph.D. Medical Officer, Center for Drug Evaluation and Research, FDA
Tuesday, December 15 th Session 19	Unit 3: 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
Monday, December 21 st	RECESS
Tuesday, December 22 nd	RECESS
Monday, December 28 th	RECESS
Tuesday, December 29 th	RECESS
Monday, January 4 th	Unit 4: Special Lecture:

Session 20	Human Genome Project and Clinical Research (1 hour) Christopher Austin, M.D. Senior Advisor to the Director for Translation Research, NHGRI
Tuesday, January 5 th Session 21	Breakout Session: Mock IRB (2 hours) Jerry Menikoff, M.D., J.D. Director, Office of Human Research Protections Office of Public Health and Science, DHHS
Monday, January 11 th Session 22	Unit 5: FDA Product Regulation (1.25 hours) Robert Yetter, Ph.D. Associate Director for Review Management Center for Biologics Evaluation and Research, FDA
Tuesday, January 12 th Session 23	Unit 6: The Clinical Researcher and the Media (45 minutes) John Burklow, M.S. Associate Director for Communications Office of Communications and Public Liaison, NIH
	Unit 7: 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, January 18 th	FEDERAL HOLIDAY
Tuesday, January 19 th Session 24	Unit 8: Data and Safety Monitoring Boards (1 hour) Dennis O. Dixon, Ph.D. Mathematical Statistician Biostatistics Research Branch, NIAID
Module III, Monitoring Patient-Oriented Research and Regulatory Issues	
Monday, January 25 th Session 25	Unit 1: 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
Tuesday, January 26 th Session 26	Unit 2: Quality Control in Clinical Trials (1 hour) Jack Guralnik, M.D., Ph.D. Chief, Epidemiology and Demography Section, NIA
Monday, February 1 st Session 27	Unit 3: Quality of Life (1 hour) John Ware, Ph.D. CEO and Chief Science Officer, QualityMetric, Inc
Tuesday, February 2 nd Session 28	Unit 4: Scientific Conduct (45 minutes) Joan Schwartz, Ph.D. Assistant Director Office of Intramural Research, NIH
Monday, February 8 th Session 29	Unit 5: NIH Peer Review Process (1 hour) Olivia Bartlett, Ph.D. Chief, Research Programs Review, NCI
Module IV, Preparing and Funding a Clinical Research Study	

Tuesday, February 9 th Session 30	Unit 1: Information Resources for Clinical Research (1 hour) Josh Duberman, M.L.I.S. Informationist/Research Librarian
Monday, February 15 th	FEDERAL HOLIDAY
Tuesday, February 16 th Session 31	Unit 2: Clinical Research from the Patient's Perspective (1 hour) Susan Butler, B.A., M.A. Vice President, Ovarian Cancer National Alliance
Monday, February 22 nd Session 32	Unit 3: 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
Tuesday, February 23 rd Session 33	Unit 4: ProtoType and Protocol Mechanics (1 hour) Philip Lightfoot, B.S., B.A. Systems Analysis, DCRI, CC
Monday, March 1 st Session 34	Unit 5: Technology Transfer (1.5 hours) Bruce Goldstein, J.D. Unit Coordinator, Technology Transfer Branch, NCI
Tuesday, March 2 nd Session 35	Unit 6: Inclusion of Women and Minorities in Clinical Trials (1 hour) Miriam Kelyt, Ph.D. Former Associate Director, Extramural Activities, NIA
Monday, March 8 th Session 36	Unit 7: 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
Tuesday, March 9 th Session 37	Unit 8: Health Disparities Research Kyu Rhee, M.D., M.P.P., FAAP, FACP Director, Office of Innovation and Program Coordination, NCMHD
Monday, March 15 th Session 38	Unit 9: Community-Based Participatory Research Francisco Sy, M.D., DrPH Chief, Office of Community Based Participatory Research and Outreach, NCMHD

*Schedule subject to change