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

October 13, 2015 – March 22, 2016

All lectures are at 5:00 p.m. (Eastern Time) in the Lipsett Amphitheater

Introduction	
Tuesday, October 13, 2015	**Welcome** (30 minutes) **John I. Gallin, M.D.**, Director, NIH Clinical Center
	History of Clinical Research: A Merging of Diverse Cultures (60 minutes) **John I. Gallin, M.D.**, Director, NIH Clinical Center Chapter: 1
Module I: Study Design, Measurement, and Statistics	
Monday, October 19, 2015 Session 1	Unit 1: **Choosing a Research Question and Implications for Efficient Clinical Trials** (90 minutes) **John Powers, III, M.D. ,** Senior Medical Scientist, National Cancer Institute (NCI) at Frederick Chapter: 19, 25, 29
Tuesday, October 20, 2015 Session 2	Unit 2: **Overview of Clinical Study Design** (90 minutes) **Laura Lee Johnson, Ph.D.,** Associate Director, Division of Biometrics III, Office of Biostatistics, Office of Translational Sciences, Center for Drug Evaluation and Research U.S. Food and Drug Administration (FDA) Chapter: 19
Monday, October 26, 2015 Session 3	Unit 3**:** **Design of Epidemiologic Studies** (90 minutes) **Laura Lee Johnson, Ph.D.,** Associate Director, Division of Biometrics III, Office of Biostatistics, Office of Translational Sciences, Center for Drug Evaluation and Research U.S. Food and Drug Administration (FDA) Chapter: 18

Tuesday, October 27, 2015 Session 4	Unit 4: **Clinical Research from the Patient's Perspective** (20 minutes) **Jerry Sachs,** Manager of Guest Services (Retired) Smithsonian Museum of Natural History Unit 5: **Study Participant Selection** (60 minutes) **Catherine Stoney, Ph.D.**, Program Director Prevention and Population Sciences Program National Heart, Lung, and Blood Institute (NHLBI) Chapter: 2, 13, 19, 26
Monday, November 2, 2015 Session 5	Unit 6: **Issues in Randomization** (90 minutes) **Paul Wakim, Ph.D.** Chief Biostatistician, Biostatistics and Clinical Epidemiology Service, NIH Clinical Center Chapter: 20, 24
Tuesday, November 3, 2015 Session 6	Unit 7: **Overview of Hypothesis Testing** (90 minutes) **Paul Wakim, Ph.D.** Chief Biostatistician, Biostatistics and Clinical Epidemiology Service, NIH Clinical Center Chapter: 21, 24
Monday, November 9, 2015 Session 7	Unit 8: **Sample Size and Power** (90 minutes) **Laura Lee Johnson, Ph.D.,** Associate Director, Division of Biometrics III, Office of Biostatistics, Office of Translational Sciences, Center for Drug Evaluation and Research U.S. Food and Drug Administration (FDA) Chapter: 22, 24
Tuesday, November 10, 2015 Day before Veterans Day No Lecture	
Monday, November 16, 2015 Session 8	Unit 9: **Conceptual Approach to Survival Analysis** (90 minutes) **Laura Lee Johnson, Ph.D.,** Associate Director, Division of Biometrics III, Office of Biostatistics, Office of Translational Sciences, Center for Drug

	Evaluation and Research U.S. Food and Drug Administration (FDA) Chapter: 23, 24
Tuesday, November 17, 2015 Session 9	Unit 10: **Measures** (90 minutes) **David Luckenbaugh, M.A.,** Biostatistician, Experimental Therapeutics and Pathophysiology Branch, National Institute of Mental Health (NIMH) Chapter: 25, 26
Monday, November 23, 2015 Thanksgiving Week No Lecture	
Tuesday, November 24, 2015 Thanksgiving Week No Lecture	
Monday, November 30, 2015 Session 10	Unit 11: **Quality of Life** (90 minutes) **Speaker: TBA** Chapter: 25
Tuesday, December 1, 2015 Session 11	Unit 12: **Designing and Testing Questionnaires** (90 minutes) **Barbara Stussman, B.A.**, Survey Statistician National Center for Complementary and Integrative Health (NCCIH) Chapter: 25
Monday, December 7, 2015 Session 12	Unit 13: **Using Large Datasets for Population-Based Health Research** (60 minutes) **Leighton Chan, M.D.**, Chief, Rehabilitation Medicine Department NIH Clinical Center Chapter: 28
Tuesday, December 8, 2015 Session 13	Unit 14: **Secondary Data/Meta-Analysis** (60 minutes) **Charles Natanson, M.D.,** Senior Investigator and Head Anesthesia Section, Critical Care Medicine Department, NIH Clinical Center

	Chapter: 27
Monday, December 14, 2015 Session 14	Unit 15: **Module I Summary and Study Examples** (90 minutes) **Laura Lee Johnson, Ph.D.,** Associate Director, Division of Biometrics III, Office of Biostatistics, Office of Translational Sciences, Center for Drug Evaluation and Research U.S. Food and Drug Administration (FDA) Chapter:
Module II: Ethical, Legal, Monitoring, and Regulatory Considerations	
Tuesday, December 15, 2015 Session 15	Unit 1: **Legal Issues in Clinical Research** (60 minutes) **Carrie Kennedy, J.D., R.N., Esq.**, Senior Attorney, HHS Office of the General Counsel, Public Health Division, National Institutes of Health Branch Chapter: 11
Monday, December 21, 2015 Christmas Week No Lecture	
Tuesday, December 22, 2015 Christmas Week No Lecture	
Monday, December 28, 2015 New Year's Week No Lecture	
Tuesday, December 29, 2015 New Year's Week No Lecture	
Monday, January 4, 2016 Session 16	Unit 2: **Ethical Principles in Clinical Research** (90 minutes) **Christine Grady, R.N., Ph.D.** Head, Section on Human Subjects Research, Chief, Bioethics Department, NIH Clinical Center Chapter: 2
Tuesday, January 5, 2016 Session 17	Unit 3: **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, January 11, 2016 Session 18	Unit 4: **Institutional Review Boards** (90 Minutes) **Jerry Menikoff, M.D., J.D**., Director, Office for Human Research Protections, Office of Public Health and Science, The U.S. Department of Health and Human Services (HHS) Chapter: 5, 6
Tuesday, January 12, 2016 Session 19	Unit 5: **Mock IRB** (120 minutes) **Jerry Menikoff, M.D., J.D.,** Director, Office for Human Research Protections, Office of Public Health and Science, The U.S. Department of Health and Human Services (HHS) Chapter: 5, 6
Monday, January 18, 2016 Martin Luther King Day No Lecture	
Tuesday, January 19, 2016 Session 20	Unit 6: **Research with Vulnerable Participants** (60 minutes) **David Wendler, Ph.D.,** Head, Unit on Vulnerable Populations, Section on Human Subjects Research, Bioethics Department, NIH Clinical Center Chapter: 2, 5
Module III: Preparing and Implementing Clinical Studies	
Monday, January 25, 2016 Session 21	Unit 1: **Developing Protocols and Manuals of Operating Procedures** (90 minutes) **Wendy Weber, N.D., Ph.D., M.P.H.** Branch Chief, Clinical Research Branch, Division of Extramural Research, National Center for Complementary and Integrative Health (NCCIH) Chapter: 29, 32
Tuesday, January 26, 2016 Session 22	Unit 2: **Evaluation of a Protocol Budget** (90 minutes) **Phyllis Klein, R.N., C.C.R.C., B.S.N.**, Director, Regulatory Support and

	Compliance, Washington University in St. Louis Chapter: 33
Monday, February 1, 2016 Session 23	Unit 3: **Scientific Conduct** (60 minutes) **James L. Gulley, M.D., Ph.D., F.A.C.P.** Director , Clinical Trials Group, Center for Cancer Research, National Cancer Institute (NCI) Chapter: 4, 12
Tuesday, February 2, 2016 Session 24	Unit 4: **Inclusion of Women and Minorities in Clinical Trials** (60 minutes) **Hannah Valantine, M.D.,** Chief Officer for Scientific Workforce Diversity, Office of the Director, NIH Chapter: 13
Monday, February 8, 2016 Session 25	Unit 5: **Pharmaceutical Development: Management of Projects** (60 minutes) **Christopher D. Breder, M.D., Ph.D.**, Clinical Team Leader, Anesthetic Products, Johns Hopkins University Chapter: 7, 26, 37, 43
Tuesday, February 9, 2016 Session 26	Unit 6: **NIH Peer Review Process** (90 minutes) **Valerie Prenger, Ph.D., M.H.S.**, Director, Office of Scientific Review, National Heart, Lung, and Blood Institute (NHLBI) Chapter: 36
Monday, February 15, 2016 Presidents' Day No Lecture	
Tuesday, February 16, 2016 Session 27	Unit 7: **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, U.S. Food and Drug Administration (FDA) Chapter: 7
Monday, February 22, 2016 Session 28	Unit 8: **Data Management & Case Report Form Development in Clinical Trials**

	(60 minutes) **Marge Good, R.N., M.P.H., O.C.N.,** Nurse Consultant Division of Cancer Prevention, Community Oncology Prevention Trials Research Group, National Cancer Institute (NCI) Chapter: 8, 33, 37
Tuesday, February 23, 2016 Session 29	Unit 9: **Electronic Health Records and Clinical Data Interchange Standards** (60 minutes) **Speaker: TBA** Chapter:34
Monday, February 29, 2016 Session 30	Unit 10: **Quality Management in Clinical Research** (60 minutes) **Elizabeth Ness, R.N., M.S.N.**, Staff Development, National Cancer Institute (NCI) Center for Cancer Research (CCR) Chapter:34, 35
Tuesday, March 1, 2016 Session 31	Unit 11: **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
Monday, March 7, 2016 Session 32	Unit 12: **Information Resources for Clinical Research** (90 minutes) **Josh Duberman, M.L.I.S.**, Informationist/Research Librarian, NIH Library Chapter: NA
Module IV: Additional Study Designs and Miscellaneous Topics	
Tuesday, March 8, 2016 Session 33	Unit 1: **Technology Transfer** (90 minutes) **Bruce Goldstein, J.D.,** Unit Coordinator, Technology Transfer Branch, National Cancer Institute (NCI) Chapter: 30, 31
Monday, March 14, 2016 Session 34	Unit 2: **Dissemination and Implementation Research** (90 minutes) **Catherine Stoney, Ph.D.**, Program Director Prevention and Population Sciences Program, National Heart, Lung, and Blood Institute (NHLBI)

	Chapter: NA
Tuesday, March 15, 2016 Session 35	Unit 3: **Health Disparities Research** (90 minutes) **Larissa Avilés-Santa, M.D., M.P.H., F.A.C.P., F.A.C.E.** Division of Cardiovascular Sciences, National Heart, Lung, and Blood Institute (NHLBI) Chapter: 46
Monday, March 21, 2016 Session 36	Unit 4: **Health Disparities and Community-Based Participatory Research** (90 minutes) **Tiffany M. Powell-Wiley, M.D., M.P.H.** Assistant Clinical Investigator, Social Determinants of Obesity and Cardiovascular Risk, Cardiovascular and Pulmonary Branch, National Heart, Lung, and Blood Institute (NHLBI) Chapter: 46
Tuesday, March 22, 2016 Session 37	Unit 5: **The Clinical Researcher and the Media** (60 minutes) **John Burklow, M.S.**, Associate Director for Communications Office of Communications and Public Liaison, NIH Chapter: 16
Monday, March 28, 2016	Reserved for makeup lecture
Tuesday, March 29, 2016	Reserved for makeup lecture