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

September 2016 – April 2017

Introduction	
	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	
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
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
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

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
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
Session 6	Unit 7: **Overview of Hypothesis Testing** (90 minutes) **Paul Wakim, Ph.D.** Chief, Biostatistics and Clinical Epidemiology Service, NIH Clinical Center Chapter: 21, 24
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
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
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
Session 10	Unit 11: **Quality of Life** (90 minutes) **Kevin Weinfurt, Ph.D.,** Professor, Department of Psychiatry and Behavioral Sciences and Department of Psychology and Neuroscience, Duke Clinical Research Institute Chapter: 25
Session 11	Unit 12: **Designing and Testing Questionnaires** (60 minutes) **Barbara Stussman, B.A.**, Survey Statistician National Center for Complementary and Integrative Health (NCCIH) Chapter: 25
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
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
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	
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
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
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
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
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
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	
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
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
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
Session 24	Unit 4: **Inclusion of Women and Minorities in Clinical Trials** (60 minutes) **Meredith D. Temple-O'Connor, Ph.D.,** Senior Scientific Advisor to the NIH Deputy Director for Extramural Research, Office of Extramural Research, Office of the Director, NIH **Janine Austin Clayton, M.D.**, NIH Associate Director for Research on Women's Health and Director, NIH Office of Research on Women's Health Chapter: 13
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
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
Session 25	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
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
Session 29	Unit 9: **Electronic Health Records and Clinical Data Interchange Standards** (60 minutes) **Stephen E. Wilson, Dr. PH.,** Director, Division of Biometrics III, Center for Drug Evaluation and Research (CDER), Office Of Biostatistics, U.S. Food and Drug Administration (FDA) Chapter:34
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
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
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	
Session 33	Unit 1: **Technology Transfer** (90 minutes) **Bruce Goldstein, J.D.,** Unit Coordinator, Technology Transfer Branch, National Cancer Institute (NCI) Chapter: 30, 31
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
Session 35	Unit 3: **Health Disparities Research** (90 minutes) **Larissa Avilés-Santa, M.D., M.P.H., FACP, FACE** Division of Cardiovascular Sciences, National Heart, Lung, and Blood Institute (NHLBI) Chapter: 46
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

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
	Final Exam Period