

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

Course Schedule

Session	Introduction
Course Introduction	<p style="text-align: center;">Welcome and History of Clinical Research: A Merging of Diverse Cultures (90 minutes)</p> <p style="text-align: center;">John I. Gallin, M.D., NIH Associate Director for Clinical Research, Chief Scientific Officer, NIH Clinical Center</p> <p style="text-align: center;">Textbook Reading: Chapter 1 Video link: https://youtu.be/402_rguPXHg</p>
	Module 1: Study Design, Measurement, and Statistics
Session 1	<p style="text-align: center;">Choosing a Research Question and Implications for Efficient Clinical Trials (90 minutes)</p> <p style="text-align: center;">John Powers, III, M.D. , Senior Medical Scientist, Collaborative Clinical Research Branch (CCRB), NIAID</p> <p style="text-align: center;">Textbook Reading: Chapters 19, 25, 29 Video link: https://www.youtube.com/watch?v=tOj9TimZU7k</p>
Session 2	<p style="text-align: center;">Overview of Clinical Study Design (90 minutes)</p> <p style="text-align: center;">Laura Lee Johnson, Ph.D., Acting 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)</p> <p style="text-align: center;">Textbook Reading: Chapter 19 Video link: https://youtu.be/8P_DTbVWu9s</p>
Session 3	<p style="text-align: center;">Design of Epidemiologic Studies (90 minutes)</p> <p style="text-align: center;">Laura Lee Johnson, Ph.D., Acting 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)</p> <p style="text-align: center;">Textbook Reading: Chapter 18 Video link: https://youtu.be/90iNvjgF27o</p>

Session 4.1	<p style="text-align: center;">Clinical Research from the Patient's Perspective (20 minutes)</p> <p style="text-align: center;">Jerry Sachs, Manager of Guest Services (Retired) Smithsonian Museum of Natural History</p> <p style="text-align: center;">Textbook Reading: Chapters 2, 13, 19, 26 Video link: https://youtu.be/FHjK1dwIpm0</p>
Session 4.2	<p style="text-align: center;">Study Participant Selection (60 minutes)</p> <p style="text-align: center;">Catherine Stoney, Ph.D., Program Director, Prevention and Population Sciences Program, National Heart, Lung, and Blood Institute (NHLBI)</p> <p style="text-align: center;">Textbook Reading: Chapters 2, 13, 19, 26 Video link: https://youtu.be/FHjK1dwIpm0</p>
Session 5	<p style="text-align: center;">Issues in Randomization (90 minutes)</p> <p style="text-align: center;">Paul Wakim, Ph.D., Chief Biostatistician, Biostatistics and Clinical Epidemiology Service, NIH Clinical Center</p> <p style="text-align: center;">Textbook Reading: Chapters 20, 24 Video link: https://youtu.be/UgFXLk7i46c</p>
Session 6	<p style="text-align: center;">Overview of Hypothesis Testing (90 minutes)</p> <p style="text-align: center;">Paul Wakim, Ph.D., Chief, Biostatistics and Clinical Epidemiology Service, NIH Clinical Center</p> <p style="text-align: center;">Textbook Reading: Chapters 21, 24 Video link: https://youtu.be/x32CZ-7ZS8Q</p>
Session 7	<p style="text-align: center;">Sample Size and Power (90 minutes)</p> <p style="text-align: center;">Laura Lee Johnson, Ph.D., Acting 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)</p> <p style="text-align: center;">Textbook Reading: Chapters 22, 24 Video link: https://youtu.be/iP_BX7YJHhw</p>
Session 8	<p style="text-align: center;">Conceptual Approach to Survival Analysis (90 minutes)</p> <p style="text-align: center;">Laura Lee Johnson, Ph.D., Acting 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)</p> <p style="text-align: center;">Textbook Reading: Chapters 23, 24</p>

	<p>Video link: https://youtu.be/dYorCZaF8ag</p>
Session 9	<p style="text-align: center;">Measures (90 minutes)</p> <p style="text-align: center;">David Luckenbaugh, M.A., Biostatistician, Experimental Therapeutics and Pathophysiology Branch, National Institute of Mental Health (NIMH)</p> <p style="text-align: center;">Textbook Reading: Chapters 25, 26 Video link: https://youtu.be/YRgTtMtfD3c</p>
Session 10	<p style="text-align: center;">Quality of Life (90 minutes)</p> <p style="text-align: center;">Kevin Weinfurt, Ph.D., Professor, Department of Psychiatry and Behavioral Sciences and Department of Psychology and Neuroscience, Duke Clinical Research Institute</p> <p style="text-align: center;">Textbook Reading: Chapter 25 Video link: https://youtu.be/Xt4CDShoUdc</p>
Session 11	<p style="text-align: center;">Designing and Testing Questionnaires (60 minutes)</p> <p style="text-align: center;">Barbara Stussman, B.A., Survey Statistician National Center for Complementary and Integrative Health (NCCIH)</p> <p style="text-align: center;">Textbook Reading: Chapter 25 Video link: https://youtu.be/X_Te5O_nwQk</p>
Session 12	<p style="text-align: center;">Using Large Datasets for Population-Based Health Research (60 minutes)</p> <p style="text-align: center;">Leighton Chan, M.D., Chief, Rehabilitation Medicine Department, NIH Clinical Center</p> <p style="text-align: center;">Textbook Reading: Chapter 28 Video link: https://youtu.be/k3EAOdlyyoU</p>
Session 13	<p style="text-align: center;">Secondary Data/Meta-Analysis (60 minutes)</p> <p style="text-align: center;">Charles Natanson, M.D., Senior Investigator and Head Anesthesia Section, Critical Care Medicine Department, NIH Clinical Center</p> <p style="text-align: center;">Textbook Reading: Chapter 27 Video link: https://youtu.be/jlAsGvMmOkY</p>
Session 14	<p style="text-align: center;">Module I Summary and Study Examples (90 minutes)</p> <p style="text-align: center;">Laura Lee Johnson, Ph.D., Acting 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)</p>

	Video link: https://youtu.be/eJVGQIQdkUY
	Module 2: Ethical, Legal, Monitoring, and Regulatory Considerations
Session 15	<p style="text-align: center;">Legal Issues in Clinical Research (60 minutes)</p> <p style="text-align: center;">Carrie Kennedy, J.D., R.N., Esq., Senior Attorney, HHS Office of the General Counsel, Public Health Division, National Institutes of Health Branch</p> <p style="text-align: center;">Textbook Reading: Chapter 11 Video link: https://youtu.be/9_YgCIHfDvw</p>
Session 16	<p style="text-align: center;">Ethical Principles in Clinical Research (90 minutes)</p> <p style="text-align: center;">Christine Grady, R.N., Ph.D. Head, Section on Human Subjects Research, Chief, Bioethics Department, NIH Clinical Center</p> <p style="text-align: center;">Textbook Reading: Chapter 2 Video link: https://youtu.be/Uihjety2d5M</p>
Session 17	<p style="text-align: center;">Data and Safety Monitoring Committees (90 minutes)</p> <p style="text-align: center;">Pamela Shaw, Ph.D., Assistant Professor, Department of Biostatistics and Epidemiology, Perelman School of Medicine, University of Pennsylvania</p> <p style="text-align: center;">Textbook Reading: Chapter 9 Video link: https://youtu.be/iYVXVg93DnY</p>
Session 18	<p style="text-align: center;">Institutional Review Boards (90 Minutes)</p> <p style="text-align: center;">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)</p> <p style="text-align: center;">Textbook Reading: Chapters 5, 6 Video link: https://youtu.be/fl8JJsQ4dCs</p>
Session 19	<p style="text-align: center;">Mock IRB (120 minutes)</p> <p style="text-align: center;">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)</p> <p style="text-align: center;">Textbook Reading: Chapters 5, 6 Video link: https://youtu.be/4S0hVogonf4</p>

Session 20	<p style="text-align: center;">Research with Vulnerable Participants (60 minutes)</p> <p style="text-align: center;">David Wendler, Ph.D., Head, Unit on Vulnerable Populations, Section on Human Subjects Research, Bioethics Department, NIH Clinical Center</p> <p style="text-align: center;">Textbook Reading: Chapters 2, 5 Video link: https://youtu.be/8OMGX-bOeJl</p>
	<p>Module III: Preparing and Implementing Clinical Studies</p>
Session 21	<p style="text-align: center;">Developing Protocols and Manuals of Operating Procedures (90 minutes)</p> <p style="text-align: center;">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)</p> <p style="text-align: center;">Textbook Reading: Chapters 29, 32 Video link: https://youtu.be/SQYAPKJ1TDg</p>
Session 22	<p style="text-align: center;">Evaluation of a Protocol Budget (90 minutes)</p> <p style="text-align: center;">Phyllis Klein, R.N., C.C.R.C., B.S.N., Director, Regulatory Support and Compliance, Washington University in St. Louis</p> <p style="text-align: center;">Textbook Reading: Chapter 33 Video link: https://youtu.be/g5XV3YkZf30</p>
Session 23	<p style="text-align: center;">Scientific Conduct (60 minutes)</p> <p style="text-align: center;">James L. Gulley, M.D., Ph.D., F.A.C.P. Director , Clinical Trials Group, Center for Cancer Research, National Cancer Institute (NCI)</p> <p style="text-align: center;">Textbook Reading: Chapters 4, 12 Video link: https://youtu.be/sUEreDQpWeg</p>
Session 24	<p style="text-align: center;">Inclusion of Women and Minorities in Clinical Trials (60 minutes)</p> <p style="text-align: center;">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</p> <p style="text-align: center;">Janine Austin Clayton, M.D., NIH Associate Director for Research on Women's Health and Director, NIH Office of Research on Women's Health</p> <p style="text-align: center;">Textbook Reading: Chapter 13 Video link: https://youtu.be/4a0e-T7-Pjc</p>

Session 25	<p style="text-align: center;">Pharmaceutical Development: Management of Projects (60 minutes)</p> <p style="text-align: center;">Christopher D. Breder, M.D., Ph.D., Clinical Team Leader, Anesthetic Products, Johns Hopkins University</p> <p style="text-align: center;">Textbook Reading: Chapters 7, 26, 37, 43 Video link: https://youtu.be/Tc5KkhrJq_E</p>
Session 26	<p style="text-align: center;">NIH Peer Review Process (90 minutes)</p> <p style="text-align: center;">Valerie Prenger, Ph.D., M.H.S., Director, Office of Scientific Review, National Heart, Lung, and Blood Institute (NHLBI)</p> <p style="text-align: center;">Textbook Reading: Chapter 36 Video link: https://youtu.be/dW1sLsnLpCM</p>
Session 25	<p style="text-align: center;">FDA Product Regulation (60 minutes)</p> <p style="text-align: center;">Christopher 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)</p> <p style="text-align: center;">Textbook Reading: Chapter 7 Video link: https://youtu.be/79TPLGB4u0k</p>
Session 28	<p style="text-align: center;">Data Management & Case Report Form Development in Clinical Trials (60 minutes)</p> <p style="text-align: center;">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)</p> <p style="text-align: center;">Textbook Reading: Chapters 8, 33, 37 Video link: https://youtu.be/IT7iSwcaPuY</p>
Session 29	<p style="text-align: center;">Electronic Health Records and Clinical Data Interchange Standards (60 minutes)</p> <p style="text-align: center;">Stephen E. Wilson, Dr. PH., Former Director, Division of Biometrics III, Center for Drug Evaluation and Research (CDER), Office Of Biostatistics, U.S. Food and Drug Administration (FDA)</p> <p style="text-align: center;">Textbook Reading: Chapter 34 Video link: https://youtu.be/e638Qaeuysk</p>
Session 30	<p style="text-align: center;">Quality Management in Clinical Research (60 minutes)</p> <p style="text-align: center;">Elizabeth Ness, R.N., M.S.N., Director, Office of Education and Compliance, Office of the Clinical Director, Center for Cancer Research (CCR),</p>

	<p>National Cancer Institute (NCI)</p> <p>Textbook Reading: Chapters 34, 35 Video link: https://youtu.be/5e7hwmaauS4</p>
Session 31	<p>Clinical Trial Registration and Results Reporting (90 minutes)</p> <p>Deborah Zarin, M.D., Assistant Director for Clinical Research Projects, Lister Hill National Medical Center for Biomedical Communications, NIH</p> <p>Textbook Reading: Chapter 15 Video link: https://youtu.be/zDoJgppJzRY</p>
Session 32	<p>Information Resources for Clinical Research (90 minutes)</p> <p>Josh Duberman, M.L.I.S., Informationist/Research Librarian, NIH Library</p> <p>Video link: https://youtu.be/jOrmcaw_7_g</p>
Module IV: Additional Study Designs and Miscellaneous Topics	
Session 33	<p>Technology Transfer (90 minutes)</p> <p>Bruce Goldstein, J.D., Monitoring & Enforcement Officer, Senior Policy Advisor, Office of Intramural Research, Office of Technology Transfer, NIH</p> <p>Textbook Reading: Chapters 30, 31 Video link: https://youtu.be/BcoOBdRCTGQ</p>
Session 34	<p>Dissemination and Implementation Research (90 minutes)</p> <p>Catherine Stoney, Ph.D., Program Director, Prevention and Population Sciences Program, National Heart, Lung, and Blood Institute (NHLBI)</p> <p>Video link: https://youtu.be/NX3tKBUqndw</p>
Session 35	<p>Health Disparities Research (90 minutes)</p> <p>Larissa Avilés-Santa, M.D., M.P.H., FACP, FACE, Division of Cardiovascular Sciences, National Heart, Lung, and Blood Institute (NHLBI)</p> <p>Textbook Reading: Chapters 13, 46 Video link: https://youtu.be/V1Cd6eIZ_Is</p>

<p>Session 36</p>	<p align="center"> 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) </p> <p align="center"> Textbook Reading: Chapters 13, 46 Video link: https://youtu.be/xCi7P5Q9g3A </p>
<p>Session 37</p>	<p align="center"> The Clinical Researcher and the Media (60 minutes) John Burklow, M.S., Associate Director for Communications, Office of Communications and Public Liaison, NIH </p> <p align="center"> Textbook Reading: Chapter 16 Video link: https://youtu.be/jxeFghp7h-o Email: BurklowJ@OD.NIH.GOV </p>
	<p align="center">Final Examination</p>