<table>
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<th>Introduction to the Principles and Practice of Clinical Research (IPPCR)</th>
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<td>September 2016 – April 2017</td>
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<tr>
<th><strong>Module I: Study Design, Measurement, and Statistics</strong></th>
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**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) |
| Session 9 | Unit 10: **Measures**  
(90 minutes)  
**David Luckenbaugh, M.A.**, Biostatistician, Experimental Therapeutics and Pathophysiology Branch, National Institute of Mental Health (NIMH) |
|---|---|
| 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 |
| Session 11 | Unit 12: **Designing and Testing Questionnaires**  
(60 minutes)  
**Barbara Stussman, B.A.**, Survey Statistician  
National Center for Complementary and Integrative Health (NCCIH) |
| 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 |
| 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 |
| 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) |
| 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 |
| 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 |
<p>| Session 25 | Unit 5: Pharmaceutical Development: Management of Projects |</p>
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<tr>
<th>Session</th>
<th>Unit</th>
<th>Chapter</th>
<th>Presenter(s)</th>
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| 26      | 6    | 7, 26, 37, 43 | Christopher D. Breder, M.D., Ph.D., Clinical Team Leader, Anesthetic Products, Johns Hopkins University | Christopher D. Breder, M.D., Ph.D., Clinical Team Leader, Anesthetic Products, Johns Hopkins University. 
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). |
| 25      | 7    | 36      | Valerie Prenger, Ph.D., M.H.S., Director, Office of Scientific Review, National Heart, Lung, and Blood Institute (NHLBI) | Valerie Prenger, Ph.D., M.H.S., Director, Office of Scientific Review, National Heart, Lung, and Blood Institute (NHLBI). 
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). |
| 28      | 8    | 8, 33, 37 | 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) | 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). 
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). |
| 29      | 9    | 34      | 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) | 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). 
Electronic Health Records and Clinical Data Interchange Standards (60 minutes) 
Elizabeth Ness, R.N., M.S.N., Staff Development, National Cancer Institute (NCI) Center for Cancer Research (CCR). |
Quality Management in Clinical Research (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). |
| 31      | 11   |          |              |         |
| Session 32 | Unit 12: Information Resources for Clinical Research (90 minutes)  
Josh Duberman, M.L.I.S., Informationist/Research Librarian, NIH Library  
Chapter: NA |
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<td><strong>Module IV: Additional Study Designs and Miscellaneous Topics</strong></td>
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| 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 |