INTRODUCTION TO THE PRINCIPLES AND PRACTICE OF CLINICAL RESEARCH

FIOCRUZ, Rio De Janeiro, Brazil

September 22 – September 26, 2014

Time	Topic	Instructor
	Monday ***September 22nd***	
8:30 - 9:15	**Welcome and Opening Address**	**Paulo Gadelha,** President of FIOCRUZ **Paulo Buss,** Director, Centro for Global Health, FIOCRUZ **Rodrigo Stabeli,**Vice-President of Research, FIOCRUZ
9:15 - 10:15	**Introduction and Program Overview** **History of Clinical Research and Overview of the National Institues of Health Clinical Center** Questions and Discussion	**John I. Gallin, M.D.** Director, National Institutes of Health Clinical Center and Associate Director for Clinical Research, National Institutes of Health
10:15 - 12:00	**Overview of Clinical Study Design** Questions and Discussion	**Laura Lee Johnson, Ph.D.** Senior Statistician, Office of Clinical and Regulatory Affairs National Center for Complementary & Alternative Medicine, National Institutes of Health
12:00 - 1:00	**Lunch**	
1:00 - 2:45	**Epidemiology and Observational Studies** Questions and Discussion	**Jerry A. Menikoff, M.D., J.D.** Director, Office for Human Research Protections, Office of the Assistant Secretary for Health, Department of Health and Human Services
2:45 - 3:00	**Break**	
3:00 - 4:15	**Introduction to Ethical Principles in Clinical Research** Questions and Discussion	**Christine Grady, MSN, Ph.D.** Chief, Department of Bioethics, National Institutes of Health Clinical Center
4:15 - 5:00	**Funding for Clinical Research in Brazil: Priorities for 2015** Questions and Discussion	**Sérgio Nishioka, M.D., Ph.D.** Coordinator, Clinical Research Division Department of Science and Technology Ministry of Health

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	Tuesday September 23rd	
8:30 - 10:30	**Issues in Randomization** Questions and Discussion	**Paul G. Wakim, Ph.D.** Team Leader, Biostatistics and Medical Informatics Team, Center for the Clinical Trials Network, National Institute on Drug Abuse, National Institutes of Health
10:30 - 10:45	**Break**	
10:45 - 12:30	**Overview of Hypothesis Testing** Questions and Discussion	**Laura Lee Johnson, Ph.D.** Senior Statistician, Office of Clinical and Regulatory Affairs National Center for Complementary & Alternative Medicine, National Institutes of Health
12:30 - 1:30	**Lunch**	
1:30 - 3:00	**Epidemiologic Approach to Evaluation of Health Programs** Questions and Discussion	**Luiz Camacho, M.D., Dr.PH.** Head of the Department of Epidemiology and Quantitative Methods in Health National School of Public Health, FIOCRUZ
3:00 - 3:15	**Break**	
3:15 - 4:15	**Conflicts of Interest and Scientifc Integrity** Questions and Discussion	**Christine Grady, MSN, Ph.D.** Chief, Department of Bioethics, National Institutes of Health Clinical Center
4:15 - 5:00	**Ethics in Clinical Research and the Brazilian Legislation** Questions and Discussion	**Jorge Venâncio, M.D.** Nacional Ethical Review Board - Comissão Nacional de Ética em Pesquisa (CONEP)

Time	Topic	Instructor
	Wednesday September 24th	
8:30 - 10:30	**Sample Size and Power** Questions and Discussion	**Paul G. Wakim, Ph.D.** Team Leader, Biostatistics and Medical Informatics Team, Center for the Clinical Trials Network, National Institute on Drug Abuse, National Institutes of Health
10:30 - 10:45	**Break**	
10:45 - 12:15	**Interpreting Common Descriptive Statistics from Clinical Research** Questions and Discussion	**Paul G. Wakim, Ph.D.** Team Leader, Biostatistics and Medical Informatics Team, Center for the Clinical Trials Network, National Institute on Drug Abuse, National Institutes of Health
12:15 - 1:15	**Lunch**	
1:15 -2:45	**Usual Care Controls in Clinical Research** Questions and Discussion	**Charles Natanson, M.D.** Senior Investigator and Head, Anesthesia Section Critical Care Medicine Department National Institutes of Health Clinical Center
2:45 - 3:30	**Clinical Research Cooperation with NIH in the Area of Infectious Diseases (AIDS): the Brazilian Experience** Questions and Discussion	**Beatriz Grinsztejn, M.D., Ph.D.** Director, STD/AIDS Clinical Research Laboratory Clinical Research Institute Evandro Chagas
3:30 - 3:45	**Break**	
3:45 - 5:00	**Study Documents: Protocols, Manuals, Case Report Forms, and Databases** Questions and Discussion	**Laura Lee Johnson, Ph.D.** Senior Statistician, Office of Clinical and Regulatory Affairs National Center for Complementary & Alternative Medicine, National Institutes of Health

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	Thursday September 25th	
8:30 - 10:15	**A Conceptual Approach to Survival Analysis** Questions and Discussion	**Laura Lee Johnson, Ph.D.** Senior Statistician, Office of Clinical and Regulatory Affairs National Center for Complementary & Alternative Medicine, National Institutes of Health
10:15 - 10:30	**Break**	
10:30 - 12:00	**Data and Safety Monitoring** Questions and Discussion	**Jerry A. Menikoff, M.D., J.D.** Director, Office for Human Research Protections, Office of the Assistant Secretary for Health, Department of Health and Human Services
12:00 - 1:00	**Lunch**	
1:00 - 2:45	**Reporting Results** Examples and Discussion	**Paul G. Wakim, Ph.D.** Team Leader, Biostatistics and Medical Informatics Team, Center for the Clinical Trials Network, National Institute on Drug Abuse, National Institutes of Health
2:45 - 4:15	**Institutional Review Boards** Questions and Discussion	**Jerry A. Menikoff, M.D., J.D.** Director, Office for Human Research Protections, Office of the Assistant Secretary for Health, Department of Health and Human Services
4:15 - 5:00	**Translational Research: From Basic Science to Clinical Research** Questions and Discussion	**Carlos Morel, M.D., Ph.D.** Director, Center for Technological Development in Health, FIOCRUZ

Time	Topic	Instructor
	Friday September 26th	
8:30 - 10:00	**Using Secondary Data in Statistical Analysis with Illustrative Examples** Questions and Discussion	**Charles Natanson, M.D.** Senior Investigator and Head, Anesthesia Section Critical Care Medicine Department National Institutes of Health Clinical Center
10:00 - 10:45	**Particular Aspects of Regulatory Issues in Brazil** Questions and Discussion	**Flavia Sobral, Ph.D.** National Health Surveillance Agency- Agência Nacional de Vigilância Sanitária (ANVISA)
10:45 - 11:00	**Break**	
11:00 - 12:00	**Summary of Content Incorporating Examples** Questions and Discussion	**Laura Lee Johnson, Ph.D.** Senior Statistician, Office of Clinical and Regulatory Affairs National Center for Complementary & Alternative Medicine, National Institutes of Health
12:00-1:00	**Lunch**	
1:00 - 1:30	**Program Evaluation**	
1:30-3:30	**Final Examination**	
3:30 - 3:45	**Break**	
3:45-4:30	**Closing Ceremony**	
4:30-5:00	**Exam Q&A**	