

**PRINCIPLES AND PRACTICE OF CLINICAL
RESEARCH**
FIOCRUZ, Rio De Janiero, Brazil
September 22 – September 26, 2014

Time	Topic	Instructor
<i>Monday</i> <i>September 22nd</i>		
8:30 - 9:15	Welcome and Opening Address	Paulo Gadelha , President of FIOCRUZ Paulo Buss , Director Center 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 Institutes 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 - 10:30	Break	
10:30 - 12:15	Overview of Clinical Study Design <i>(topic to be confirmed)</i> Questions and Discussion	Dr. Luiz Camacho FIOCRUZ, Nacional School for Puclic Heath - Escola Nacional de Saúde Pública Sérgio Arouca (ENSP)
12:15 - 1:15	Lunch	
1:15 - 3:00	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

3:00 - 3:15

Break

3:15 - 5:00

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

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

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

3:00-3:15

Break

3:15 - 4:00

**Ethics in Clinical Research and the Brazilian
Legislation**
Questions and Discussion

Representante da CONEP
National Ethical Review Board - Comissão Nacional
de Ética em Pesquisa (CONEP)

4:00 - 5:00

Conflicts of Interest and Scientific Integrity

Christine Grady, MSN, Ph.D.

Chief, Department of Bioethics, National Institutes of
Health Clinical Center

**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 - 2:00	Translational Research: From Basic Science to Clinical Research Questions and Discussion	Dr. Carlos Morel FIOCRUZ, Center for Technological Development in Health - Centro de Desenvolvimento Tecnológico em Saúde (CDTS)
2:00 - 2:30	Funding for Clinical Research in Brazil: Priorities for 2015	Dr. Sérgio Nishioka Ministry of Health. Science and Technology Department- DECIT
2:30 - 3:00	Cooperation with NIH in infectious diseases area (AIDS): cooperation with NIH Questions and discussion	Dr. Beatriz Grinsztejn FIOCRUZ, National Institute of Infectology - Instituto de Infectologia Evandro Chagas (INI)
3:00 - 3:30	Break	

3:30 - 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

**Thursday
September 25th**

8:30 - 10:30	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
10:30 - 10:45	Break	
10:45 - 12:15	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
12:15 - 1:15	Lunch	
1:15 - 3:00	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
3:00 - 3:30	Break	
3:30 - 5:00	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

**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 - 10:15
Break

10:15 - 11:15
Particular Aspects of Regulatory Issues in Brazil
Questions and Discussion

Dr. Patrícia Andreotti
National Health Surveillance Agency- Agência
Nacional de
Vigilância Sanitária (ANVISA)

11:15 - 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