INTRODUCTION TO THE PRINCIPLES

AND PRACTICE OF CLINICAL RESEARCH

From the National Institutes of Health Clinical Center

Hosted by Department of Medicine, Loma Linda University
11234 Anderson Street, Loma Linda, CA 92354

October 14, 2014 to March 9, 2015

This course will be offered live, via web broadcasting from **2:00- 3:30 PM**.
Archived viewing of the lectures will also be available via the NIH website, for the convenience of registered participants.
Syllabus will be posted identifying meeting dates, locations, and topics.
A certificate will be awarded upon completion of the course, including a final exam.

Topics

- Choosing a Research Question
- Design of Epidemiologic Studies and Study Development
- Using Secondary Data and Meta Analysis
- Opportunities for Innovation in Clinical Research
- Measures
- Participant Selection
- Issues in Randomization
- Overview of Hypothesis Testing
- Sample Size and Power
- Conceptual Approach to Survival Analysis
- Designing and Testing Questionnaires
- Economic Analysis in Clinical Research
- Quality of Life
- Inclusion of Women and Minorities in Clinical Trials
- Researching an Ethics Question
- Legal Issues in Clinical Research
- Information Resources for Clinical Research
- Community Based Participatory Research
- Scientific Conduct
- Protocol Mechanics
- Concepts in the Management of Projects
- Data Management in Clinical Trials
- Quality Control in Clinical Trials
- FDA Product Regulation
- The Clinical Researcher and the Media
- Data and Safety Monitoring Boards
- Evaluation of a Protocol Budget
- NIH Peer Review Process
- Technology Transfer
- Evaluation of Alternative and Complementary Therapies
- Ethical Principles in Clinical Research
- Design of Case Report Forms
- Mock Institutional Review Boards
- Clinical Research from a Patient's Perspective
- Health Disparities Research
- Team Science

Course Objectives

To become familiar with the basic epidemiologic methods involved in clinical research.
To be able to discuss the principles involved in the ethics of clinical research, the legal issues involved in clinical research, and the regulations involved in human subjects research, including the role of IRBs in clinical research.
To become familiar with the principles and issues involved in monitoring patient-oriented research.
To be able to discuss the infrastructure required in performing clinical research and to have an understanding of the steps involved in developing and funding research studies.

There is no charge for the course; however, the textbook, Principles and Practice of Clinical Research, Third Edition is suggested as supplemental information for the course. For more information please contact:

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DEADLINE FOR REGISTRATION IS OCTOBER 6, 2014

Introduction to the Principles and Practice of Clinical Research (IPPCR)
October 14, 2014 – March 9, 2015
From the National Institutes of Health Clinical Center
Hosted by the Department of Medicine, Loma Linda University
The FIRST Session will meet from 1:30 PM to 3:30 PM.
Thereafter, all sessions will meet on **Mondays** and **Tuesdays**
From **2:00 – 3:30** PM, PST

Date Session #	Location LLUMC	Topic(s)
Tuesday, October 14, 2014	A-Level Amphitheater *Please note – this is the only class that begins at 1:30 PM instead of 2:00 PM	Welcome (30 minutes) John I. Gallin, M.D. Director NIH Clinical Center
		History of Clinical Research: A Merging of Diverse Cultures (30 minutes) John I. Gallin, M.D. Director NIH Clinical Center **Chapter: 1**
Module I: Study Design and Statistics		
Monday, October 20, 2014 Session 1	A-Level Amphitheater	**Unit 1:** Choosing a Research Question and Implications for Efficient Clinical Trials (90 minutes) John Powers, III, M.D. Senior Medical Scientist, NCI Frederick **Chapter: 19, 25, 29**
Tuesday, October 21, 2014 Session 2	MC 1584	**Unit 2:** Clinical Research from the Patient's Perspective (30 minutes) Jerry Sachs Manager of Guest Services (Retired) Smithsonian Museum of Natural History **Chapter: 17** **Unit 3:** Study Participant Selection (60 minutes) Catherine Stoney, Ph.D. Program Director Prevention and Population Sciences Program, NHLBI **Chapter: 2, 13, 19, 26; Please review archived video on** Inclusion of Women and Minorities in Clinical Trials (60 minutes) by Miriam Kelty, Ph.D. **prior to this lecture**

Monday, October 27, 2014 Session 3	MC 1584	**Unit 4:** Overview of Clinical Study Design (90 minutes) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM **Chapter: 19**
Tuesday, October 28, 2014 Session 4	MC1584	**Unit 5:** Measures (60 minutes) David Luckenbaugh, Ph.D. Biostatistician Experimental Therapeutics and Pathophysiology Branch, NIMH **Chapter: 25, 26**
Monday, November 3, 2014 Session 5	MC 1584	**Unit 6:** Design of Epidemiologic Studies (90 minutes) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM **Chapter: 18**
Tuesday, November 4, 2014 Session 6	MC 1584	**Unit 7:** Issues in Randomization (90 minutes) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM **Chapter: 20, 24**
Thursday, November 6, 2014 Breakout Session	N/A This session will not be broadcasted	Breakout Session (60 minutes) Title – TBD Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM
Monday, November 10, 2014 Session 7	TBD	**Unit 8:** Using Large Datasets for Population-Based Health Research (60 minutes) Leighton Chan, M.D. Chief, Rehabilitation Medicine Department, CC **Chapter: 28**
Tuesday, November 11, 2014 FEDERAL HOLIDAY Veterans Day	N/A No class today	NO LECTURE

Monday, November 17, 2014 Session 8	TBD	**Unit 9:** Overview of Hypothesis Testing (90 minutes) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM **Chapter: 21, 24**
Tuesday, November 18, 2014 Session 9	TBD	**Unit 10:** Sample Size and Power (90 minutes) Laura Lee Johnson, Ph.D. Office of Clinical and Regulatory Affairs, NCCAM **Chapter: 22, 24**
Thursday, November 20, 2014 Breakout Session	N/A This session will not be broadcasted	Breakout Session (60 minutes) Title – TBD Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM
Monday, November 24, 2014 and Tuesday, November 25, 2014 Recess	N/A No class	**Week of Thanksgiving-**NO SCHEDULED LECTURES; MAKE-UP LECTURES AS NEEDED
Monday, December 1, 2014 Session 10	TBD	**Unit 11**: Designing and Testing Questionnaires (60 minutes) Gordon Willis, Ph.D. Cognitive Psychologist Applied Research Program, NCI **Chapter: 25**
Tuesday, December 2, 2014 Session 11	TBD	**Unit 12:** Conceptual Approach to Survival Analysis (90 minutes) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM **Chapter: 23, 24**
Thursday, December 4, 2014 Breakout Session	N/A This session will not be broadcasted	Breakout Session – Laura Lee Johnson Office of Clinical and Regulatory Affairs, NCCAM

Monday, December 8, 2014 Session 12	TBD	**Unit 13:** Secondary Data/Meta-Analysis (90 minutes) Charles Natanson, M.D. Senior Investigator and Head Anesthesia Section Critical Care Medicine Department, CC **Chapter: 27**
Tuesday, December 9, 2014 Session 13	TBD	**Unit 14:** Module I Summary and Study Examples (90 minutes) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM **Chapter:**
Module II: Ethical, Legal, and Regulatory Considerations		
Monday, December 15, 2014 Session 14	TBD	**Unit 1:** Ethical Principles in Clinical Research (60 minutes) Christine Grady, R.N., Ph.D. Head, Section on Human Subjects Research Chief, Bioethics Department, CC **Chapter: 2**
Tuesday, December 16, 2014 Session 15	TBD	**Unit 2:** 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, FDA **Chapter: 7**
Monday, December 22, 2014 through Tuesday, December 30, 2014 Recess	N/A No class	**Holiday Recess-**NO LECTURES
Monday, January 5, 2015 Session 16	TBD	**Unit 3:** Institutional Review Boards (90 Minutes) Jerry Menikoff, M.D., J.D. Director, Office for Human Research Protections

		Office of Public Health and Science, DHHS **Chapter: 5, 6**
Tuesday, January 6, 2015 Session 17	TBD	**Unit 4: Mock IRB (120 minutes)** Jerry Menikoff, M.D., J.D. Director, Office for Human Research Protections Office of Public Health and Science, DHHS **Chapter: 5, 6**
Monday, January 12, 2015 Session 18	TBD	**Unit 5**: Research with Vulnerable Participants (60 minutes) David Wendler, Ph.D. Head, Unit on Vulnerable Populations Section on Human Subjects Research, Bioethics Department, CC **Chapter: 2, 5**
Module III: Preparing and Monitoring Clinical Studies		
Tuesday, January 13, 2015 Session 19	TBD	**Unit 1:** Information Resources for Clinical Research (90 minutes) Josh Duberman, M.L.I.S. Informationist/Research Librarian, NIH Library **Chapter:**
Monday, January 19, 2015 FEDERAL HOLIDAY Martin Luther King Day	TBD	NO LECTURE
Tuesday, January 20, 2015 Session 20	TBD	**Unit 2:** Protocol Development (60 minutes) Wendy Weber, N.D., Ph.D., M.P.H. Program Officer Division of Extramural Research, NCCAM **Chapter: 29, 32** **Unit 3:** Protocol Mechanics and Tools (30 minutes) Philip Lightfoot, B.S., B.A. Systems Analysis Department of Clinical Research Informatics, CC

		Chapter: 32
Monday, January 26, 2015 Session 21	TBD	**Unit 4:** Pharmaceutical Development: Management of Projects (60 minutes) **Chapter:** **7, 26,** **37, 43**
Tuesday, January 27, 2015 Session 22	TBD	**Unit 5:** Evaluation of a Protocol Budget (90 minutes) Phyllis Klein, R.N., CCRC, BSN Director, Regulatory Support and Compliance Washington University in St. Louis **Chapter: 33; prior to the lecture review archived video on** Development of Manuals of Operating Procedures (90 minutes) by Wendy Weber, N.D., Ph.D., M.P.H.
Monday, February 2, 2015 Session 23	TBD	**Unit 6:** NIH Peer Review Process (90 minutes) Valerie Prenger, Ph.D., M.H.S. Director Office of Scientific Review, NHLBI **Chapter: 36**
Tuesday, February 3, 2015 Session 24	TBD	**Unit 7:** Design of Case Report Forms (30 minutes) Diane St. Germain, R.N., M.S., C.R.N.P. Nurse Consultant Division of Cancer Prevention, NCI **Chapter: 33, 37** **Unit 8:** Data Management in Clinical Trials (30 minutes) Diane St. Germain, R.N., M.S., C.R.N.P. Nurse Consultant Division of Cancer Prevention, NCI **Chapter: 8**
Monday, February 9, 2015 Session 25	TBD	**Unit 9:** Basic Data Representation (60 minutes) Jim Cimino, M.D. Chief

		Laboratory for Informatics Development, CC **Chapter:**
Tuesday, February 10, 2015 Session 26	TBD	**Unit 10:** Data & Non-Data Aspects of Quality Control in Clinical Studies (60 minutes) Elizabeth Ness, R.N., MSN Staff Development NCI/CCR **Chapter:**
Monday, February 16, 2015 FEDERAL HOLIDAY President's Day	N/A – No Class	NO LECTURE
Tuesday, February 17, 2015 Session 27	TBD	**Unit 11:** 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**
Monday, February 23, 2015 Session 28	TBD	**Unit 12:** 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**
Module IV: Miscellaneous Topics		
Tuesday, February 24, 2015 Session 29	TBD	**Unit 1:** Technology Transfer (90 minutes) Bruce Goldstein, J.D. Unit Coordinator Technology Transfer Branch, NCI **Chapter: 30, 31**

Monday, March 2, 2015 Session 30	TBD	**Unit 2:** Scientific Conduct (60 minutes) James L. Gulley, M.D., Ph.D., F.A.C.P. Director Clinical Trials Group, Center for Cancer Research, NCI **Chapter: 4, 12**
Tuesday, March 3, 2015 Session 31	TBD	**Unit 3:** Health Disparities Research (60 minutes) Larissa Avilés-Santa, M.D., M.P.H., F.A.C.P., F.A.C.E. Division of Cardiovascular Sciences, NHLBI **Chapter: 46**
Monday, March 9, 2015 Session 32	TBD	**Unit 4:** Community-Based Participatory Research (30 minutes) Francisco Sy, M.D., Dr PH Director Division of Extramural Activities and Science Programs, NIMHD **Chapter: 46** **Unit 5:** Dissemination and Implementation Research (60 minutes) Catherine Stoney, Ph.D. Program Director Prevention and Population Sciences Program, NHLBI **Chapter:**

Lectures to be Viewed on Archives	
Please view lecture prior to Dr. Catherine Stoney's October 21, 2014 lecture: "Study Participant Selection"	**Inclusion of Women and Minorities in Clinical Trials** (60 minutes) Miriam Kelty, Ph.D. Special Volunteer Former Associate Director, Extramural Activities, NIA **Chapter: 13**
Please view lecture prior to Dr. Laura Lee Johnson's December 2, 2014 lecture: "Conceptual Approach to	**Quality of Life** (45 minutes) John Ware, Ph.D. Chief Science Officer

Survival Analysis”	John Ware Research Group, Inc. **Chapter: 25**
	The Clinical Researcher and the Media (45 minutes) John Burklow, M.S. Associate Director for Communications Office of Communications and Public Liaison, NIH **Chapter: 16**
	Legal Issues in Clinical Research (60 minutes) Carrie Pottker-Fishel, J.D. Attorney Advisor Office of General Counsel, NIH **Chapter: 11**
Please view lecture after Wendy Weber’s January 20, 2015 lecture: “Protocol Development” and prior to Phyllis Klein’s January 27, 2015 lecture: “Evaluation of a Protocol Budget”	**Development of Manuals of Operating Procedures** (90 minutes) Wendy Weber, N.D., Ph.D., M.P.H. Program Director Division of Extramural Research, NCCAM **Chapter: 29**