



# Harvard Medical School

## Department of Continuing Education

Offered By

Department of Physical Medicine and Rehabilitation - Spaulding Rehabilitation Hospital

# PRINCIPLES AND PRACTICE OF CLINICAL RESEARCH

## *International Distance-Learning Clinical Research Training Program*

Course Director: **Felipe Fregni, MD, PhD, MPH**  
ASSOCIATE PROFESSOR, HARVARD MEDICAL SCHOOL

**February – November 2012**  
**Courtyard Marriott – Cambridge, MA**

### **What You Can Expect**

The collaborative distance-learning program in Clinical Trials is offered to participants from Boston and throughout the world. This course is designed for individuals who wish to gain basic advanced training in clinical trials before moving into the field and for those who have experience in this area and aim to broaden their role in the design, management, analysis, and reporting of clinical trials. Participants can earn up to 72 credits (or 118 with the optional 4-day workshop and optional 2-day Statistical workshop in São Paulo, Brazil) *AMA PRA Category 1 credit(s)*<sup>™</sup>.



Please contact: [info@clinicalresearchlearning.org](mailto:info@clinicalresearchlearning.org) for more information

[www.clinicalresearchlearning.org](http://www.clinicalresearchlearning.org)

# Principles and Practice of Clinical Research

## DESCRIPTION:

Despite the critical importance of clinical research for advancements in medicine, it is still immature in most of the medical specialties and in addition, many clinicians cannot evaluate research evidence critically. The purpose of our course is to offer a highly interactive learning environment for clinical research training internationally and also to create a global network of clinical researchers to foster future collaboration in clinical research.

Our program covers from the basics of clinical research (such as: how to formulate a research question, select study population, randomization and blinding methods) to statistical methods (data distribution and classification, statistical tests, sample size calculation, survival analysis, missing data, and meta-analysis); data collection, monitoring and reporting (including training in manuscript writing); and study designs (observational studies, non-inferior and adaptive designs and randomized clinical trials).

## LEARNING FORMAT:

This course is a distance-learning course; however, participants have to attend weekly 3-hour interactive videoconference sessions. Videoconference sessions are broadcast live from Harvard to different centers across the world. Participants may enroll as part of a site center, or individually if a site center is not accessible to them. Our program consists of 24 lectures taught by faculty from Harvard Medical School, Harvard School of Public Health and Boston University. Additionally, each weekly lecture includes a required online discussion forum and an online poll addressing the topic. Participants are required to complete weekly homework assignments, including some statistical exercises. Participants are required to work in a group project using the online interactive Wiki tool. Podcasts and recordings of the lectures are posted weekly. At the end of the course, there will be an optional 4-day intensive workshop to practice the concepts learned in this course in Sao Paulo, Brazil.

**LEARNING OBJECTIVES:** At the end of the course, participants will be able to design clinical trials in an effective manner, collect data properly, use the basic functions of a statistical software, choose appropriate basic statistical tests, critically read and understand a research paper, understand basics of article publication and review and more.

**TARGET AUDIENCE:** Applicants usually have a graduate degree or a health care professional degree (MD, MPH, biostatistics, epidemiology, nursing, physical and speech therapy, or dentistry) and they come from several countries since participants can take this course in their hometown.

**Course Site: Courtyard Marriott Cambridge, 777 Memorial Drive, Cambridge, MA 02139. Telephone: 617-492-7777**

**TECHNICAL REQUIREMENTS:** All participants must have a computer with excellent Internet connection, webcam, and microphone. Sites must have videoconference technology and technicians.

**COURSE DATES AND TUITION FEES:** Distance Learning: February - November 2012

Optional 4-Day Workshop in São Paulo, Brazil: October 25-28, 2012

Optional 2-Day Statistical Workshop in São Paulo, Brazil: October 23-24, 2012

Distance Learning, Onsite Workshop (Sao Paulo), book + Stata Software + 2-Day Statistical Workshop - \$8,500.00

Distance Learning and Onsite Workshop in Sao Paulo plus book and Stata Software - \$7,000.00

Distance Learning and Onsite Workshop in Sao Paulo - \$6,500.00

Distance Learning plus book and Stata Software - \$5,500.00

Distance Learning Component - \$5,000.00

Residents/Fellows plus book and Stata Software - \$3,000.00

Residents and Fellows in Training - \$2,500.00

4-Day Alumni Workshop - \$1,500.00

2-Day Statistical Workshop - \$1,500.00

**APPLICATION AND COURSE ADMISSION:** Registration is limited. Please submit the following documents online: curriculum vitae and letter stating the reason to participate in the course. Application is due by January 31, 2012. Contact us at [info@clinicalresearchlearning.org](mailto:info@clinicalresearchlearning.org) for late application consideration.

## INTERNATIONAL SITES AND CONTACTS:

USP – São Paulo, Brazil: *Dr. Wu Tu Hsing* – [wu@fmusp.org.br](mailto:wu@fmusp.org.br)

ISPRM – International site: *Dr. Marta Imamura* – [martaimf@gmail.com](mailto:martaimf@gmail.com)

FCMMG – Belo Horizonte, Brazil: *Dr. Mariana Lopes* – [mazalua@yahoo.com](mailto:mazalua@yahoo.com)

Universidad de Cuenca – Cuenca, Ecuador: *Dr. Arturo Carpio* – [Arturo.carpio@ucuenca.edu.ec](mailto:Arturo.carpio@ucuenca.edu.ec)

Coimbra University Hospital – Coimbra, Portugal: *Dr. Monteiro* – [pedromonte@gmail.com](mailto:pedromonte@gmail.com)

Instituto Etica – Salvador, Bahia: *Dr. Juleilda Nunes* – [curso.pesquisa@yahoo.com.br](mailto:curso.pesquisa@yahoo.com.br)

UFRGS – Porto Alegre, Brazil: *Dr. Wolnei Caumo* – [caumo@cpovo.net](mailto:caumo@cpovo.net)

UNICAMP – Campinas, Brazil: *Dr. Heitor Moreno Junior* - [hmoreno@uol.com.br](mailto:hmoreno@uol.com.br)

PUCE – Quito, Ecuador: *Dr. Edison Chaves* – [echaves@puce.edu.ec](mailto:echaves@puce.edu.ec)

USMP – Lima, Peru: *Dr. Tamara Jorquiera* [tjorquiera@usmp.edu.pe](mailto:tjorquiera@usmp.edu.pe)

FCV – Salvador, Colombia: *Dr. Ronald Garcia* – [ronaldgarcia@fcv.org](mailto:ronaldgarcia@fcv.org)

*\* Individuals from other locations can still enroll and take the course using Adobe Connect*

**ACCREDITATION:** The Harvard Medical School is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. The Harvard Medical School designates this live activity for a maximum of 118 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity. Course Only: A maximum of 72 *AMA PRA Category 1 Credits™*. Optional 4-day workshop in Brazil: A maximum of 31.25 *AMA PRA Category 1 Credits™*. Optional 2-day Statistical workshop: A maximum of 14.75 *AMA PRA Category 1 Credits™*. This course is designed to meet the following ACGME competencies: Medical Knowledge, Practice-based Learning and Improvement, and Professionalism.

# Program Schedule 2012

## 6-month distance learning (or live learning in Boston): Course Schedule

**Module One – Basics of Clinical Research:**  
**Tutorial Lecture - 23 February, 2012:**  
**Course Staff and Course Director**  
*Opening Remarks*

**Lecture 1 - 15 March 2012: Steve Freedman**  
*Introduction to Clinical Trials*

**Lecture 2 - 22 March 2012: Felipe Fregni**  
*Selection of the Questions*

**Lecture 3 - 29 March 2012: Michele Hacker**  
*Study Population*

**Lecture 4 - 05 April 2012: David Wypij**  
*Basic Study Design*

**Online discussion: Ethical and regulatory issues**

**Lecture 5 - 12 April 2012: Joseph Massaro**  
*Study Blinding*

**Lecture 6 - 26 April 2012: David Wypij**  
*The Randomization Process*

**Lecture 7 - 03 May 2012:**  
**Paul Conlin**  
*Recruitment of Study Participants*  
**Lotfi Merabet**  
*Participant Adherence*

**Module Two - Statistics:**

**Lecture 8, 10 May 2012 - Roger Davis**  
*Statistics - Basics*

**Clinician Statistical Corner - Munir Boodhwani**  
*Data classification and Sample Size Calculation in clinical research*

**Lecture 9 - 17 May 2012: Jessica Paulus**  
*Sample Size*

**Lecture 10 - 24 May 2012: Felipe Fregni**  
*Statistical Tests I*

**Lecture 11 - 31 May 2012: Felipe Fregni**  
*Statistical Tests II*

**Lecture 12 - 07 June 2012: Roger Davis**  
*Survival Analysis*

**Lecture 13 - 14 June 2012: Felipe Fregni**  
*Other Issues in Statistics I*

**Lecture 14 - 21 June 2012: Felipe Fregni**  
*Other Issues in Statistics II*

**Module Three – Practical Aspects of Clinical Research:**

**Lecture 15 - 28 June 2012: Gretchen Brodnicki**  
*Integrity in Research*

**Lecture 16 – 16 August 2012: Dennis LaCroix**  
*The Business of Clinical Research*  
**Vera Novak**  
*Being a Clinical and Translational Scientist*

**Lecture 17 - 23 August 2012: Alan Zaslavsky**  
*Design and Analysis of Surveys*

**Lecture 18 - 30 August 2012: John Ferguson**  
*Assessing risk and adverse effects in clinical research*  
**Suzanne George**  
*Phase III and Multicenter Trials*

**Lecture 19 - 06 September 2012: Caren Solomon**  
*Manuscript submission*

**Module Four – Study Design:**  
**Online discussion: International/global research**

**Lecture 20 - 13 September 2012: Scott Evans**  
*Non-inferiority designs*

**Lecture 21 - 20 September 2012:**

**Clarissa Valim**  
*Observational Studies*

**Lecture 22 - 27 September 2012: Laura Mauri**  
*Confounders in observational studies: using the method of propensity score*

**Lecture 23 - 04 October 2012: Richard Kuntz**  
*Other Designs*

**Lecture 24 - 11 October 2012: Merit Cudkowicz**  
*Experimental Design - Randomized Clinical Trials*

*Final Exam will be scheduled in November after the 4-Day Live intensive course.*

## FACULTY:

Felipe Fregni, MD, PhD, MPH  
(Harvard Medical School)

Munir Boodhwani, MD, MSc (University of Ottawa)

Gretchen Brodnicki, JD  
(Harvard Medical School)

Paul Conlin, MD  
(Harvard Medical School)

Merit Cudkowicz, MD  
(Harvard Medical School)

Roger Davis, ScD  
(Harvard School of Public Health)

Jessica Elder, ScD  
(Harvard School of Public Health)

Scott Evans, PhD  
(Harvard School of Public Health)

John Ferguson, MD  
(Novartis Vaccines and Diagnostics)

Steve Freedman, MD, PhD  
(Harvard Medical School)

Suzanne George, MD  
(Harvard Medical School)

Michele Hacker, ScD  
(Harvard School of Public Health)

Donald Halstead  
(Harvard School of Public Health)

Christine Jesser, PhD  
(Harvard School of Public Health)

Richard Kuntz, MD  
(Harvard Medical School)

Dennis LaCroix, JD  
(Genzyme)

Joseph Massaro, PhD  
(Boston University School of Public Health)

Laura Mauri, MSc  
(Harvard Medical School)

Lotfi Merabet, OD, PhD  
(Harvard Medical School)

Vera Novak, MD, PhD  
(Harvard Medical School)

Jessica Paulus, ScD  
(Tufts University School of Medicine)

Lauren Dewey Platt, PhD  
(Harvard Medical School)

Caren Solomon, MD  
(Harvard Medical School)

Clarissa Valim, ScD, MD  
(Harvard School of Public Health)

David Wypij, PhD  
(Harvard School of Public Health)

Alan Zaslavsky, PhD  
(Harvard Medical School)

## Optional 2-Day Statistical Workshop in São Paulo, Brazil: Course Schedule

Tuesday, October 23, 2012

**Correlation and Causality**  
7:00 – 8:00 Registration  
8:00 – 8:15 Welcome  
8:15 – 9:00 The Basics of Correlation and Causality  
9:00 – 9:45 Statistical Tests  
9:45 – 10:00 Break  
10:00 – 12:00 Practical Applications  
12:00 – 1:00 Lunch

**Linear Regression**  
1:00 – 1:45 Assumptions for Regression  
1:45 – 2:30 Transformations to Achieve Linearity  
2:30 – 2:45 Break  
2:45 – 3:30 Confounding and Correlation  
3:30 – 4:15 Simple Linear Regression  
4:15 – 5:00 Multiple Linear Regression

Wednesday, October 24, 2012

**Logistic Regression**  
8:00 – 8:45 Categorical Variables  
8:45 – 9:45 Construction of Models  
9:45 – 10:00 Break  
10:00 – 11:00 Special Situations

**ANOVA**  
11:00 – 12:00 Assumptions for Using ANOVA  
12:00 – 1:00 Lunch  
1:00 – 2:00 ANOVA – Single Factor  
2:00 – 3:00 ANOVA – Multifactor  
3:00 – 3:15 – Break

**Other Issues Related to Regression Modeling**  
3:15 – 4:00 Interaction and Quadratic Effects  
4:00 – 5:00 Regression Modeling in Practice

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# Program Schedule 2012

## Optional 4-Day Workshop in São Paulo, Brazil: Course Schedule

### THURSDAY, OCTOBER 25, 2012

7:00 – 8:00 Registration  
8:00 – 8:15 Welcome!  
8:15 – 9:00 Bias - Lotfi Merabet  
9:00 – 9:45 Randomization – Jessica Paulus  
9:54 – 10:00 Break  
10:00 – 12:00 Small Group Discussion  
12:00 – 1:00 Lunch  
1:00 – 2:00 Individual Office Hours with Speakers  
2:00 – 5:00 Small Group Discussions

### FRIDAY, OCTOBER 26, 2012

8:00 – 8:30 Group Exercise  
8:30- 9:15 Statistical Review – Roger Davis  
9:15 – 10:30 Statistical Review – Clarissa Valim  
10:30 – 12:00 Small Group Discussions  
12:00 – 1:00 Lunch  
1:00 – 2:00 Individual Office Hours with Speakers  
2:00 – 4:00 Small Group Discussions  
4:00 – 5:00 Group Project Summary  
5:00 – 6:00 Optional Session: Journal Club – Lauren Dewey Platt  
6:00 – 8:00 Celebration and Awards

### SATURDAY, OCTOBER 27, 2012

8:00 – 10:00 Group Project Presentations  
10:00 – 11:00 Leadership in Clinical Research – Lauren Dewey Platt  
11:00 – 12:00 Case Discussion on Pragmatic Trials – Felipe Fregni  
12:00 – 12:30 Guidelines for the Grant Writing Workshop – Donald Halstead  
12:30 – 1:30 Lunch  
1:20 – 5:00 Manuscript/Grant Writing Workshop – Donald Halstead  
5:00 – 6:00 Practical Activity

### SUNDAY, OCTOBER 28, 2012

8:00 – 9:00 Working with Investigators: Designing Clinical Research Projects I – Christine Jesser  
9:00 – 10:00 Working with Investigators: Designing Clinical Research Projects II – Jessica Elder  
10:00 – 12:00 Writing Style: Some Advice to Improve Your Manuscript Before Submission – Donald Halstead  
12:00 – 1:00 Lunch  
1:00 – 2:30 Practical Exercises: Experience with Manuscript Submission – Felipe Fregni  
2:30 – 4:45 Manuscript Review Workshop  
4:45 – 5:00 Closing Remarks

The optional 4-day live intensive course will host ten Harvard professors who will review and discuss material presented throughout the year in a detailed and intensive fashion. One important part of the 4-day live course is that students will review their group projects with the Harvard faculty. Also, students will have a 2-day practical Manuscript Writing workshop with Prof. Donald Halstead from Harvard School of Public Health. This 4-day live course is an important component and is intended to give students hands on experience in clinical trials design and analysis.

**DISCLOSURE POLICY:**  
Harvard Medical School (HMS) adheres to all ACCME Essential Areas, Standards, and Policies. It is HMS's policy that those who have influenced the content of a CME activity (e.g. planners, faculty, authors, reviewers and others) disclose all relevant financial relationships with commercial entities so that HMS may identify and resolve any conflicts of interest prior to the activity. These disclosures will be provided in the activity materials along with disclosure of any commercial support received for the activity. Additionally, faculty members have been instructed to disclose any limitations of data and unlabeled or investigational uses of products during their presentations.

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## Participating International Sites:

