



January 16, 2015
OAICE-DG-3-1-2015

Felipe Fregni, M.D., PhD., M.P.H.
Director, Laboratory of Neuromodulation,
Department of Physical Medicine & Rehabilitation,
CNY Bldg 79/96 13th Street
Charlestown, MA 02129

UCR FM 13:58 19/01/15

Dear Dr. Fregni

We are pleased to inform you that the University of Costa Rica is very interested to collaborate with your prestigious University on the distance learning training program "Principles and Practice of Clinical Research".

Last Tuesday, we had a meeting with Dr. Luis Bernardo Villalobos, Dean of the Faculty of Medicine, Dr. Jaime Fornaguera, Director of the Neuroscience Center, and Dr. Gabriel Torrealba, Lecturer and faculty of the School of Medicine. They explained to us the importance of this course and its strategic value for our faculty and researchers from the different health related schools and departments.

Dr. Torrealba mentioned that the idea of offering this course in Costa Rica has received a very positive response from his colleagues. As a result 15 of them have already signed in to take it. Dr. Villalobos has agreed to provide the space and necessary equipment and facilities (computers and high speed internet connection) for the course.

We have no doubts that this course will be very helpful for our faculty and students and hopefully will become the first step for joint collaboration between our institutions.

Taking into account the high academic standards of the course organized by your Medical School and Hospital and the good response by our faculty and students as mentioned above, which has exceeded the minimum number of 10 participants required, we would respectfully ask you if it is possible for you to award scholarships (tuition waiver) for other students who would be very interested to attend the course, but can not afford it.

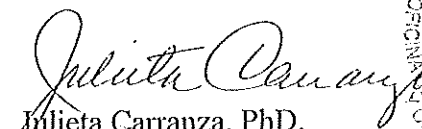


OAICE-3-1-2015

Página 2

We appreciate your kind invitation to the University of Costa Rica to become one of your teaching centers for your distance learning training program "Principles and Practice of Clinical Research". We look forward to establishing this collaboration.

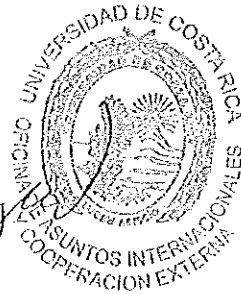
Sincerely,



Julieta Carranza, PhD.

Director

Office of International Affairs and External
Cooperation



C: Bernal Herrera, PhD. Vice Rector of Academic Affairs

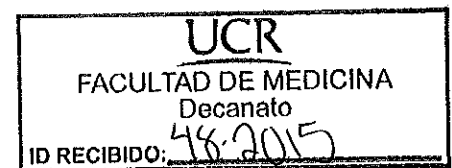
Cecilia Diaz, PhD., Dean of Graduate Studies

Luis Bernardo Villalobos, MD, Dean of the Faculty of Medicine

Jaime Fornaguera, PhD., Director, Neuroscience Center

Gabriel Torrealba, MD, School of Medicine

COPIA





HARVARD MEDICAL SCHOOL



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MASSACHUSETTS
GENERAL HOSPITAL

Felipe Fregni, M.D., Ph.D., M.P.H.

*Associate Professor of Physical
Medicine & Rehabilitation
Associate Professor of Neurology
Harvard Medical School*

*Director, Laboratory of Neuromodulation,
Department of Physical Medicine & Rehabilitation,
Spaulding Rehabilitation Hospital &
Massachusetts General Hospital*

*Director, CME Principles and
Practice of Clinical Research,
International Clinical Research
Training Program*

Gabriel Torrealba, MD

11.11.14

Dear Dr. Torrealba,

I am delighted to invite you to be the Site Director of the 2015 Principles and Practice of Clinical Research (PPCR) at Universidad de Costa Rica, Costa Rica starting on 01.01.2015. PPCR is a course offered by the Department of Physical Medicine & Rehabilitation, Spaulding Rehabilitation Hospital and Massachusetts General Hospital and provided by Harvard Medical School. As we discussed, the Site Director is responsible for the overall operation of the international PPCR site as outlined below:

Site Director Responsibilities:

- Ensure that the overall operation of the site supports the educational mission of PPCR.
- Provide support to site students.
- Organize local infrastructure for weekly PPCR lectures in your site.
- Maintain strong and frequent communication with Boston/PPCR staff.
- Coordinate and participate in 2015 PPCR activities.

We have no doubts that the Site Director has an important mission for the success of the site and overall learning of students. A strong Site Director has many characteristics that combine leadership, community building skills, and administrative duties.

We hope you accept this invitation to be part of the PPCR team in 2015 as a Site Director of Costa Rica. I look forward to working with you.

Yours sincerely

Sincerely,

Felipe Fregni, MD PhD MPH

Laboratory of Neuromodulation
CNY Bldg 79/96 13th Street
Charlestown, MA 02129

Tel: 617.952.6156
www.neuromodulationlab.org
<http://pmr.hms.harvard.edu/pages/57/100/>



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GENERAL HOSPITAL

Felipe Fregni, M.D., Ph.D., M.P.H.

*Associate Professor of Physical
Medicine & Rehabilitation
Associate Professor of Neurology
Harvard Medical School*

*Director, Laboratory of Neuromodulation,
Department of Physical Medicine & Rehabilitation,
Spaulding Rehabilitation Hospital &
Massachusetts General Hospital*

*Director, CME Principles and
Practice of Clinical Research,
International Clinical Research
Training Program*

Julietta Carranza, PhD
Office of International Affairs and External Cooperation
Universidad de Costa Rica

January 13, 2015

Dear Dr. Carranza,

I am delighted to collaborate with Universidad de Costa Rica, and work together for the opening of the first center in Central America, for the 2015 Principles and Practice of Clinical Research (PPCR) course. PPCR is a course offered by the Department of Physical Medicine & Rehabilitation, Spaulding Rehabilitation Hospital and Massachusetts General Hospital, and provided by Harvard Medical School.

Our collaborative distance-learning training program in clinical research – PPCR - is offered to participants from Boston and throughout the world. It is designed for individuals who wish to gain basic and 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. At the end of the course, participants will be able to design clinical trials in an effective manner, collect data appropriately, use the basic functions of a statistical software package, choose appropriate basic statistical tests, run statistical analysis, critically read and understand a research paper, develop clinical research based on integrity principles, design a basic survey, discuss the basics of article publication and the reviewing process, and describe more complex clinical trial designs.

Certain benefits for your institution should be acknowledged with the participation in this academic initiative. By helping clinical researchers and professors of your institution to improve their skills in a highly interactive environment with clinical researchers across different countries, this program will promote personal and professional growth and make clinical researchers more effective in their work. We also expect that the interactive environment of our course will promote connections among participants and therefore foster future collaborative multicenter projects. Our program also offers the possibility, through the Clinical Research Fellow Practice workshop, to enhance practical research skills in Boston.

We have already contacted Dr. Miguel A. Barboza Elizondo from the Escuela de Tecnologías en Salud and the Neuroscience Department in Hospital Calderón Guardia (former student of the PPCR 2014 program), and Dr. Gabriel Torrealba from the Anatomy Department of your University, to collaborate with PPCR-2015 as local Site Directors. There will be no financial support from PPCR for such role, and they have accepted this challenge.

We have no doubt that this collaborative program would bring great benefits to the scientific community in your university and the clinical researchers across your country.

Yours Sincerely,

A handwritten signature in black ink, appearing to read 'Fregni', with a large loop at the beginning and a trailing flourish.

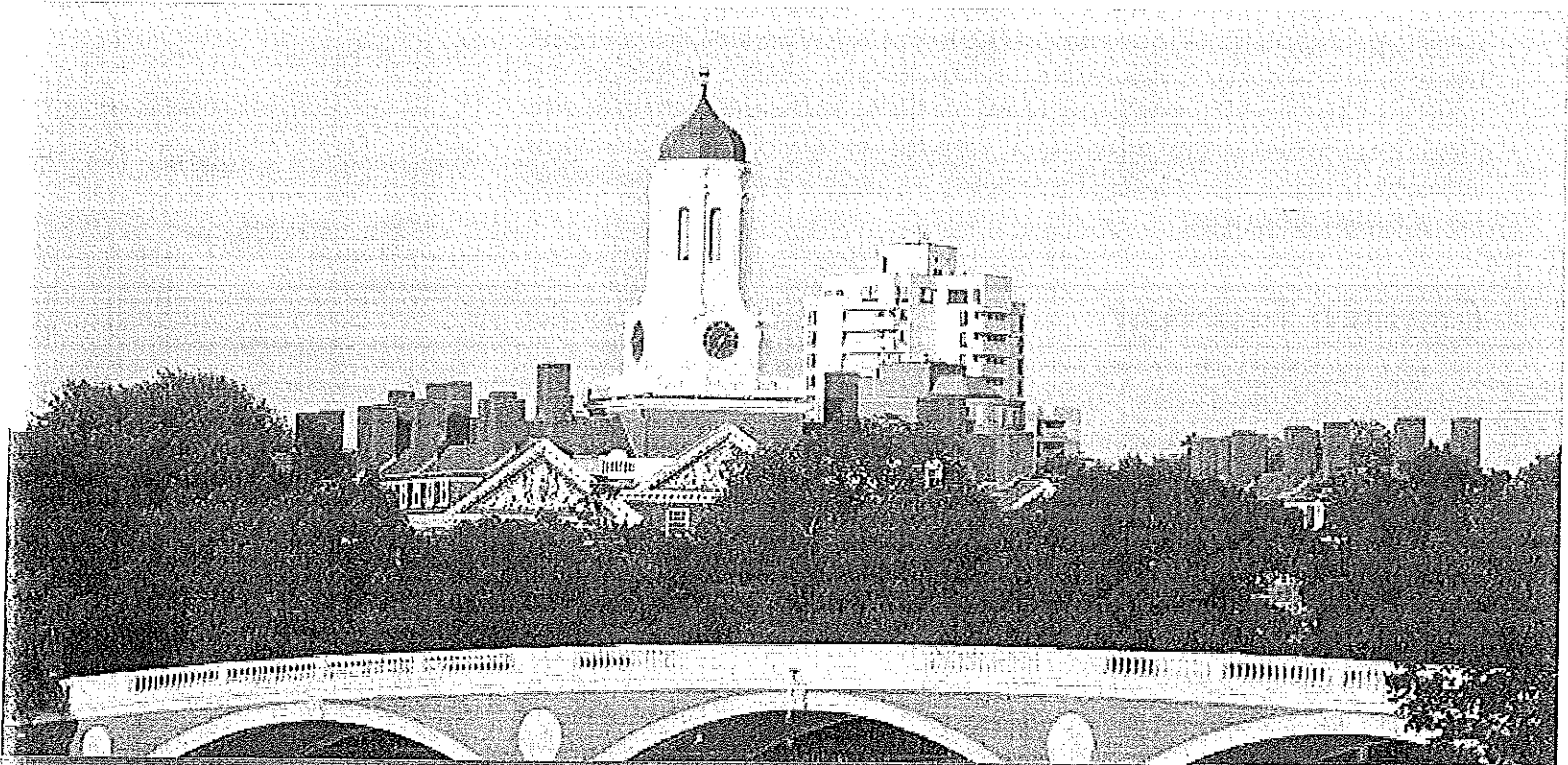
Felipe Fregni, MD, PhD, MPH

cc. Luis B. Villalobos, MD, MSc
Jaime Fornaguera, PhD
Miguel Barboza, MD
Gabriel Torrealba, MD



HARVARD MEDICAL SCHOOL

Provided by Harvard Medical School
Offered by the Department of Physical Medicine and Rehabilitation,
Spaulding Rehabilitation Hospital & Massachusetts General Hospital



PRINCIPLES AND PRACTICE OF CLINICAL RESEARCH

International Distance-Learning Clinical Research Training Program

February – November 2015

Course Director – Felipe Fregni, MD, PhD, MPH, MEd
Associate Professor, Harvard Medical School



This collaborative and interactive distance-learning program in Clinical Research is offered to participants from Boston and throughout the world. The course is designed for individuals who wish to gain basic and 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.



Description

Clinical research is critically important for advancements in medicine; however its implementation is still immature in most of the medical specialties. 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 the basics of clinical research (including: how to formulate a research question, select study population, randomization and blinding methods), statistical methods (data distribution and classification, statistical tests, sample size and power calculation, survival analysis, missing data, and meta-analysis), data collection, monitoring and reporting (including training in manuscript writing), and study designs (non-inferiority and adaptive designs and observational and randomized clinical trials).

Course Format

This course has a blended format with live (via web or in a site center) and online interaction. Participants have to attend weekly 3-hour interactive videoconference sessions. In addition we offer five live workshops (four in Boston and one abroad) in which participants can deepen their knowledge and meet face to face with Harvard University Faculty). Videoconference sessions are broadcast live from Harvard to 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 distinguished faculty from Harvard Medical School and Harvard School of Public Health. This course uses the case method to enhance learning. Cases were developed for each lecture and participants are expected to discuss these cases. Additionally, each weekly lecture is supplemented by mandatory participation in online discussions and an online poll addressing the week's topic. Participants are required to complete weekly assignments that emphasize statistical exercises and to work in a group project using an online interactive Wiki tool. Podcasts and recordings of the lectures are posted weekly. At the end of the course, a 5-day intensive workshop is offered to practice the concepts learned in this course.

Learning Objectives

At the end of the course, participants will be able to design clinical trials and interpret results from statistical analysis in an effective manner, collect data appropriately, use the basic functions of a statistical software package, choose appropriate basic statistical tests, run statistical analysis, critically read and understand a research paper, develop clinical research based on integrity principles, design a basic survey, discuss the basics of article publication and the reviewing process, and describe more complex clinical trial designs.

Target Audience

Applicants come from all over the world and usually have a graduate degree or a health care professional degree (MD, MPH, biostatistics, epidemiology, nursing, physical and speech therapy, or dentistry).

Technical Requirements

All participants must have a computer with excellent internet connection, webcam, and microphone. Site centers must be equipped with videoconference technology and have technicians available.

INTERNATIONAL SITES AND CONTACTS

Harvard Medical School - Boston, MA
Felipe Fregni, MD, PhD, MPH, MEd

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* Individuals from other locations can still enroll and take the course.

9-Month Main Course Component

(via live site center or live webcast)

Module One

Basics of Clinical Research

Tutorial Lecture, 26 February 2015 – Course Staff and PPCR Course Director - Felipe Fregni

Lecture 1 - 19 March 2015: Steve Freedman
Introduction to Clinical Trials

Lecture 2 – 26 March 2015: Jonathan S. Williams
Selection of the Questions

Lecture 3 – 02 April 2015: Michele Hacker
Study Population

Online discussion: Ethical and regulatory issues

Lecture 4 - 09 April 2015: David Wypij
Basic Study Design

Lecture 5 – 16 April 2015: Joseph Massaro
Study Blinding

Lecture 6 – 23 April 2015:
Priscilla Driscoll-Shempp
Recruitment of Study Participants
&
Lotfi Merabet
Participant Adherence

Lecture 7 - 30 April 2015: David Wypij
The Randomization process

Module Two

Statistics

Lecture 8 - 14 May 2015: Roger Davis
Statistics - Basics

Lecture 9 – 21 May 2015: Farzad Noubary
Statistical Tests I

Lecture 10 - 28 May 2015: Farzad Noubary
Statistical Tests II

Lecture 11 - 04 June 2015: Jessica Paulus
Sample Size

Lecture 12 - 11 June 2015: Roger Davis
Survival Analysis

Lecture 13 – 18 June 2015: Felipe Fregni
Other Issues in Statistics I

Lecture 14 – 25 June 2015: Felipe Fregni
Other Issues in Statistics II

Module Three

Practical Aspects of Clinical Research

Lecture 15 – 02 July 2015:

Mark Barnes
Integrity in Research
&
Suzanne George
Phase III and Multicenter Trials

6-Week Statistical Study Period

Lecture 16 – 13 August 2015: Alan Zaslavsky
Design and Analysis of Surveys

Lecture 17 - 20 August 2015: John Ferguson
Assessing risk and adverse effects in clinical research

Lecture 18 - 27 August 2015:
Karen Lodigiani & Jennifer Meneses
The Business of Clinical Research – Negotiating contracts
&
Donald Halstead
Manuscript Writing

Lecture 19 – 03 September 2015: Caren Solomon
Manuscript submission

Module Four

Study Designs

Lecture 20 - 10 September 2015:
Scott Evans
Non-inferiority designs

Lecture 21 - 17 September 2015:
Richard Kuntz
Other Designs

Lecture 22 – 24 September 2015:
Clarissa Valim
Observational Studies

Lecture 23 - 01 October 2015:
Robert Yeh
Confounders in observational studies: using the
method of propensity score

Lecture 24 – 08 October 2015:
Shelley Tworoger & Felipe Fregni
Special Panel: RCT vs. Observational Designs – how
to choose?

FACULTY:

Felipe Fregni, MD, PhD, MPH, MEd
Harvard Medical School

Roger Davis, ScD
Harvard School of Public Health

Priscilla Driscoll-Shempp, MD
Harvard Clinical Research Institute

Scott Evans, PhD
Harvard School of Public Health

John Ferguson, MD
Novartis Vaccines and Diagnostics

Steven Freedman, MD, PhD
Harvard Medical School

Suzanne George, MD
Harvard Medical School

Michele Hacker, PhD
Beth Israel Deaconess Medical Center

Kathryn E. Hall, MS, RNCS, ANP-BC
Massachusetts General Hospital

Donald Halstead
Harvard School of Public Health

Leslie Howes, MPH, CIP
Harvard School of Public Health

Richard Kuntz, MD
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Karen Lodigiani
Partners Healthcare Office

Joseph Massaro, PhD
Boston University School of Public Health

Jennifer Meneses
Partners Healthcare Office

Lotfi Merabet, OD, PhD
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Farzad Noubary, PhD
Tufts Medical Center

Jessica Paulus, ScD
Tufts University School of Medicine

Ian Shempp, MA
Brigham and Women's Hospital

Caren Solomon, MD
Harvard Medical School

Shelley Tworoger, PhD
Harvard School of Public Health

Clarissa Valim, ScD, MD
Harvard School of Public Health

Jonathan S. Williams, MD
Harvard Medical School

David Wypij, PhD
Harvard School of Public Health

Robert Yeh, MD
Harvard Medical School

Alan Zaslavsky, PhD
Harvard Medical School



DISCLOSURE POLICY

Harvard Medical School 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.

Application and Course Admission

Registration is limited. Please submit the following documents online at www.ppcr.hms.harvard.edu/registration: Curriculum Vitae, letter of intent stating the reason to participate in the course and letter of recommendation. Application is due by December 31, 2014. Late application will be considered on a case-by-case basis.

Course Dates

9-Month Distance Learning Main Course Component	February - November, 2015
Optional 5-Day Workshop	October 20 - 24, 2015
Clinical Research Fellow Practice Workshop	February - December, 2015
Optional 2-Day Study Coordinator Workshop	July 13 - 14, 2015
Optional 2-Day Statistical Workshop	July 16 - 17, 2015
Optional Introductory Workshop and Evidence-Based Medicine	March 9 - 10, 2015

Course Tuition Fees

All registration prices include a 1-year Small Stata 13 (GradPlans™) license. Shipping is included. Main component includes 5-day workshop.

Main Component + Three Workshops	\$10,000.00
Main Component + Two Workshops	\$9,500.00
Main Component + One Workshops	\$8,500.00
Main Course Component (includes 5-day workshop)	\$7,500.00
Residents & Fellows Main Component	\$3,750.00
Main Course Component (includes 5-day workshop) - Group or Site Center	\$3,500.00
Clinical Research Fellow Practice Workshop	\$1,750.00
2-Day Statistical Workshop (with three-week online component)	\$1,500.00
2-Day Study Coordinator Workshop (with three-week online component)	\$1,500.00
Independent 5-Day Workshop	\$1,500.00
Introductory Workshop and Evidence-Based Medicine	\$1,500.00

Refunds, less an administrative fee of \$75, will be issued for all cancellations received two weeks prior to the start of the course. Refund requests must be received by postal mail, email, or fax. No refund will be issued should cancellation occur less than two weeks prior. "No shows" are subject to the full course fee and no refunds will be issued once the conference has started.

5-DAY WORKSHOP

The optional 5-day live intensive course will host Harvard and other Boston professors who will review and discuss material presented throughout the year in a detailed and intensive fashion. One important part of the 5-day live course is that students will review their group projects with the Harvard faculty. Also, students will have a practical Manuscript Writing workshop with Prof. Donald Halstead from Harvard School of Public Health. This 5-day live course is an important component and is intended to give students hands on experience in clinical trials design and analysis.

Tuesday, October 20, 2015 Introduction and Group Project Preparation

04:30pm – 05:00pm	Registration
05:00pm – 05:15pm	Introduction – Felipe Fregni
05:15pm – 06:00pm	Bias – Lotfi Merabet
06:00pm – 06:45pm	Case Discussion on Pragmatic Trials – Felipe Fregni
06:45pm – 08:00pm	Small Group Discussions

Wednesday, October 21, 2015 Group Project – Design, Regulatory and Management Issues

08:00am – 08:45am	Lecture – special topic I – Jess Paulus
08:45am – 12:00pm	Small Group Discussions
12:00pm – 04:00pm	Break
02:00pm – 04:00pm	Individual Office Hours with Speakers (optional)
04:00pm – 05:00pm	Small Group Discussions
05:00pm – 08:00pm	Manuscript Writing Workshop – Part I – Donald Halstead

Thursday, October 22, 2015 Group Project Workshop – Statistical Review

08:00am – 08:45am	Lecture – special topic II – Roger Davis
08:45am – 12:00pm	Small Group Discussions
12:00pm – 04:00pm	Break
12:00pm – 04:00pm	Special Statistical Office Hours with Prof. Farzad (slots of 30min): data analysis, data interpretation and other statistical questions.
02:00pm – 04:00pm	Individual Office Hours with Speakers (optional)
03:00pm – 04:00pm	Meeting for 2015 participants interested in being PPCR 2016 TAs
04:00pm – 05:00pm	Clarissa Valim: statistical analysis with large datasets
05:00pm – 08:00pm	Manuscript Writing Workshop – Part II – Donald Halstead

Friday, October 23, 2015 Manuscript Writing and Submission

08:00am – 08:45am	Lecture – Special Topic III – Jess Paulus
08:45am – 12:00pm	Small Group Discussions
12:00pm – 04:00pm	Break
02:00pm – 04:00pm	Individual Office Hours with Speakers (optional)
03:00pm – 04:00pm	Real life Statistics II – Clarissa Valim and Faculty Facilitators (optional – Alumni and current participants)
04:00pm – 05:00pm	Group Project presentation to Faculty – small groups with Faculty – final presentation and preliminary grading for bonus points
05:00pm – 08:00pm	Manuscript Writing Workshop – part III – Donald Halstead
08:00pm – 09:00pm	Break
09:00pm – 11:00pm	Celebration and Awards with dinner

Saturday, October 24, 2015 Manuscript Submission and Post-Submission

08:00am – 10:30am	Final Group Project Presentations – final grading
10:30am – 11:00am	Award - best group project for two projects (all participants of the two best projects will be awarded a special certificate)
11:00am – 11:45am	Practical Exercise and wrap-up – Felipe Fregni
11:45am – 12:00pm	Closing Remarks - Faculty Members

FACULTY

Felipe Fregni, MD, PhD, MPH, MEd
Harvard Medical School
Roger Davis, ScD
Harvard Medical School
Jessica Elder, PhD, MPH
Burke Medical Research Institute
Donald Halstead
Harvard School of Public Health
Lotfi Merabet, OD, PhD
Harvard Medical School
Farzad Noubary, PhD
Tufts Medical Center
Jessica Paulus, ScD
Harvard School of Public Health; Tufts University
Clarissa Valim, ScD, MD
Harvard School of Public Health

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 177.5 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.
Core Course Only: A maximum of 75 AMA PRA Category 1 Credits™
Optional Clinical Research Fellow Workshop: A maximum of 27 AMA PRA Category 1 Credits™
Optional 2-day Statistics Workshop: A maximum of 15 AMA PRA Category 1 Credits™
Optional 5-day BRAZIL Workshop: A maximum of 31.5 AMA PRA Category 1 Credits™
Optional 2-day Study Coordinator Workshop: A maximum of 15.25 AMA PRA Category 1 Credits™
Optional 2-day Introductory EBM Workshop: 13.75 AMA PRA Category 1 Credits™.
This course is designed to meet the following ACGME competencies: Medical Knowledge, Practice-based Learning and Improvement and Professionalism.

CLINICAL RESEARCH FELLOW PRACTICE, BOSTON

Formerly known as the Latin American Initiative, the course aims to enhance the interest in Clinical and Basic Science research in developing countries by offering the opportunity to learn and practice research skills. The objective is to train future clinician investigators who will become leaders for international collaboration in medical clinical research and medical education. Accepted participants will come to Boston for one year, and be enrolled in the Principles and Practice of Clinical Research (PPCR) main course component. Participants will have to be in a Boston laboratory as a research fellow and develop in parallel a project based on their practical laboratory experience. We will assist with placement in Boston laboratories, but the final decision for acceptance in the Boston laboratories will come from the laboratory directors. However, acceptance for this program will come from PPCR. Participants will also be an integral part of the Practice Workshop organizational team and share their work with health care professionals from different parts of the globe. The participants will work on research projects and, therefore, have the opportunity to become co-authors in future publications.

Meeting 1 - April 2, 2015

7:00pm - 8:30pm Welcome and general instructions, Introduction of program, Main goals and expectations - Prof. Fregni

Meeting 2 - April 23, 2015

7:00pm - 8:30pm 10 minute presentation of research project and review proposal - I - Prof. Fregni

Meeting 3 - May 7, 2015

7:00pm - 8:30pm 10 minute presentation of research project and review proposal - II - Prof. Fregni

Meeting 4 - June 28, 2015

7:00pm - 8:30pm Practical challenges in clinical research - Prof. Ivan Rosas

Meeting 5 - June 25, 2015

7:00pm - 8:30pm Update of projects and mid-course evaluation - Prof. Fregni

Meeting 6 - August 27, 2015

7:00pm - 8:30pm Practical challenges in basic research - Prof. Friehs

Meeting 7 - September 24, 2015

7:00pm - 8:30pm Setting up a laboratory and future career opportunities - Prof. Merabet

Meeting 8 - November 5, 2015

7:00pm - 8:30pm Mentoring in clinical research - Prof. Ivan Rosas

Meeting 9 - February 4, 2016

7:00pm - 8:30pm Final presentation of projects and review papers and final evaluation - Prof. Fregni



FACULTY/SPEAKERS

Felipe Fregni, MD, PhD, MPH, MEd
Harvard Medical School

Ingeborgh Friehs, MD
Children's Hospital Boston

Linda Godfrey, MSN, ACNS, BC
Harvard School of Public Health

Lotfi Merabet, OD, PhD
Harvard Medical School

Ivan Rosas, MD
Harvard Medical School

Lucinda Williams, MSN, RN
Harvard Catalyst Clinical Research Center



STUDY COORDINATOR WORKSHOP, BOSTON

The 2-day live intensive course will host five Harvard professors and directors of clinical research centers at Harvard affiliated hospitals who will teach the theoretical and practical aspects of being a study coordinator in a detailed and intensive fashion and will be critical for PPCR students who want to become or are currently study coordinators and plan for a future career as a study coordinator. Topics will include subject recruitment, budgeting, staffing, regulatory issues (IRB, HIPAA, FDA), reporting of adverse events, informed consent, electronic medical records, study data management (databases, data entry, forms), drug storage and monitoring, study adherence, management and leadership in clinical research. During the workshop students will conduct practical exercises in study groups and develop a study project.

Monday, July 13, 2015

07:00am – 08:00am	Registration
08:00am – 08:15am	Welcome!
Initiating a Study	
08:15am – 09:00am	Initiating a Study I: site selection
09:00am – 09:45am	Initiating a study II: assessing feasibility (recruitment, budget, staffing)
09:45am – 10:00am	Break
10:00am – 12:00am	Practical Exercises I: students will be divided in groups and choose sites and negotiate agreements with mock sites
12:00am – 01:00pm	Lunch
First Steps	
01:00pm – 01:45pm	Regulatory Issues (IRB, HIPAA and FDA)
01:45pm – 02:30pm	Study first steps I (Informed consent, paperwork, electronic medical records)
02:30pm – 2:45pm	Break
02:45pm – 3:30pm	Study first steps II (recruitment strategies)

03:30pm – 5:00pm	Practical exercises II: students will be divided in groups and create paperwork organization for their study and create recruitment strategies
05:00pm – 6:00pm	Management and leadership in clinical research

Tuesday, July 14, 2015

Study Activities	
08:00am – 08:45am	Study activities I (General tracking procedures, forms and study folders, software programs)
08:45am – 09:45am	Study activities II (Drug storage, monitoring drugs and monitoring visits)
09:45am – 10:00am	Break
10:00am – 10:30am	Study activities III (Improving study adherence)
10:30am – 12:00pm	Practical exercises II: students will be divided in groups and define strategies to manage trials
12:00pm – 12:30pm	Lunch
12:30pm – 03:30pm	Final project presentation and group discussion

FACULTY

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DISCLOSURE POLICY

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2-DAY STATISTICAL WORKSHOP, BOSTON

This workshop serves as additional statistical training for participants from PPCR who wish to learn more advanced statistical methods. During the course, STATA (same platform used in PPCR) will be used. Participants will have an opportunity to review and expand their statistical knowledge and will be prepared to practically apply their skills to their own research. During the classes, participants will be asked to work with data sets, how to fit a model, how to conduct statistical tests in STATA and how to read and interpret the STATA output. After the workshop, participants will be familiar with the challenges, limitations and issues of analyzing data and interpreting the results, which will help them to better read the scientific literature, to better review manuscripts and to write their own manuscripts and grants.

Thursday, July 16, 2015

Modeling Continuous Data (Faculty: David Wypij, Felipe Fregni)

07:00am – 08:00am Registration

08:00am – 08:15am Welcome!

Correlation and Causality

08:15am – 09:00am The Basics of Correlation and Causality

09:00am – 09:45am Statistical Tests

09:45am – 10:00am Break

10:00am – 12:00am Practical Applications

12:00am – 01:00pm Lunch

Linear Regression

01:00pm – 01:45pm Assumptions for Regression

01:45pm – 02:30pm Transformations to Achieve Linearity

02:30pm – 2:45pm Break

02:45pm – 3:30pm Confounding and Correlation

03:30pm – 4:15pm Simple Linear Regression

04:15pm – 5:00pm Multiple Linear Regression

Friday, July 17, 2015

Modeling Categorical Data (Faculty: Clarissa Valim, Felipe Fregni)

07:00am – 08:00am Breakfast

Logistic Regression

8:00am – 8:45am Categorical Variables

8:45am – 9:45am Construction of Models

9:45am – 10:00am Break

10:00am – 11:00am Special Situations

Logistic Regression

11:00am – 12:00am Assumptions for Logistic Regression

12:00am – 1:00pm Lunch

1:00pm – 2:00pm Model Building with Logistic Regression

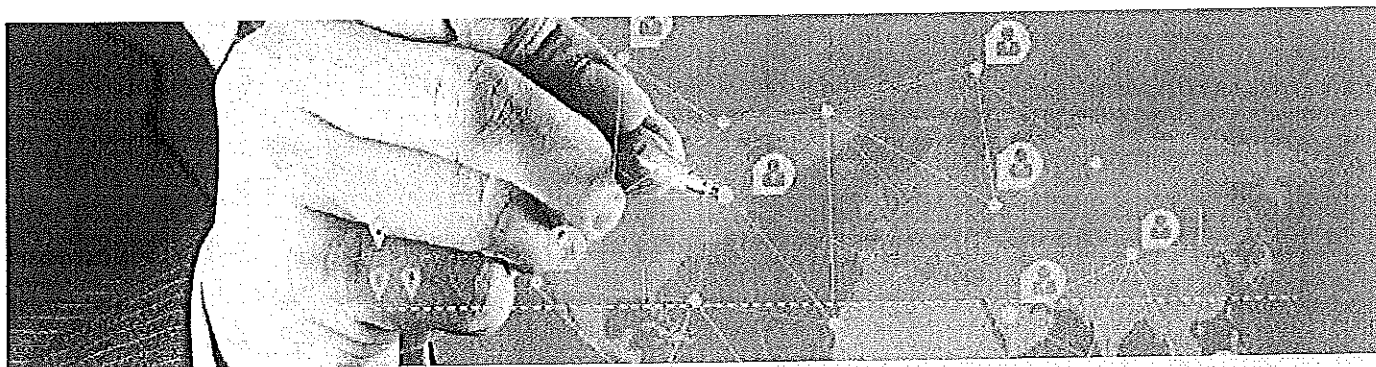
2:00pm – 3:00pm Model fit and confounding

3:00pm – 3:15pm Break

Student Presentation

3:15pm – 4:00pm Interaction and Quadratic Effects

4:00pm – 5:00pm Regression Modeling in Practice



FACULTY

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Harvard Medical School

Clarissa Valim, ScD, MD
Harvard School of Public Health

David Wypij, PhD
Harvard School of Public Health



INTRODUCTORY WORKSHOP AND EVIDENCE-BASED MEDICINE, BOSTON

This Workshop is an introduction about the importance of Evidence Based-Medicine. In this workshop participants of PPCR will also get to know each other and discuss the importance of knowing the principles of Evidence Based-Medicine. This will be an important Workshop for the participants taking the PPCR course, especially for those who are taking the course in order to improve their clinical skills.

Monday, March 9, 2015

Study Activities

08:00am – 08:45am	Registration
08:45am – 09:45am	Goals and expectations of Principles and Practice of Clinical Research
09:45am – 10:00am	Students Introduction and brief presentation
10:00am – 10:30am	Break
10:30am – 12:00pm	Practical Exercises on Importance of EBM
12:00pm – Afternoon	Practical Exercises in group and preparation of next day

Tuesday, March 10, 2015

07:00am – 08:00am	Breakfast
08:00am – 08:50am	History of Scientific Investigation
08:50am – 09:40am	Why Evidence-Based Medicine
09:40am – 10:30am	Clinician vs. research perspective in Medicine-Based Evidence
Assessing Medical/Research Information	
10:30am – 11:20am	Methods of access and databases
11:20am – 12:10pm	Advanced searches
12:10pm – 01:10pm	Lunch
01:10pm – 02:00pm	Limitation and challenges of searching

02:00pm – 02:50pm	Keeping up with medical literature
Accessing the validity of medical information	
02:50pm – 03:40pm	Medical Evidence
03:40pm – 04:30pm	Randomized clinical trials, Observational Studies and Case reports – assessing quality of evidence – practical exercise

FACULTY

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