Harvard Medical School

Department of Continuing Education

Offered By
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

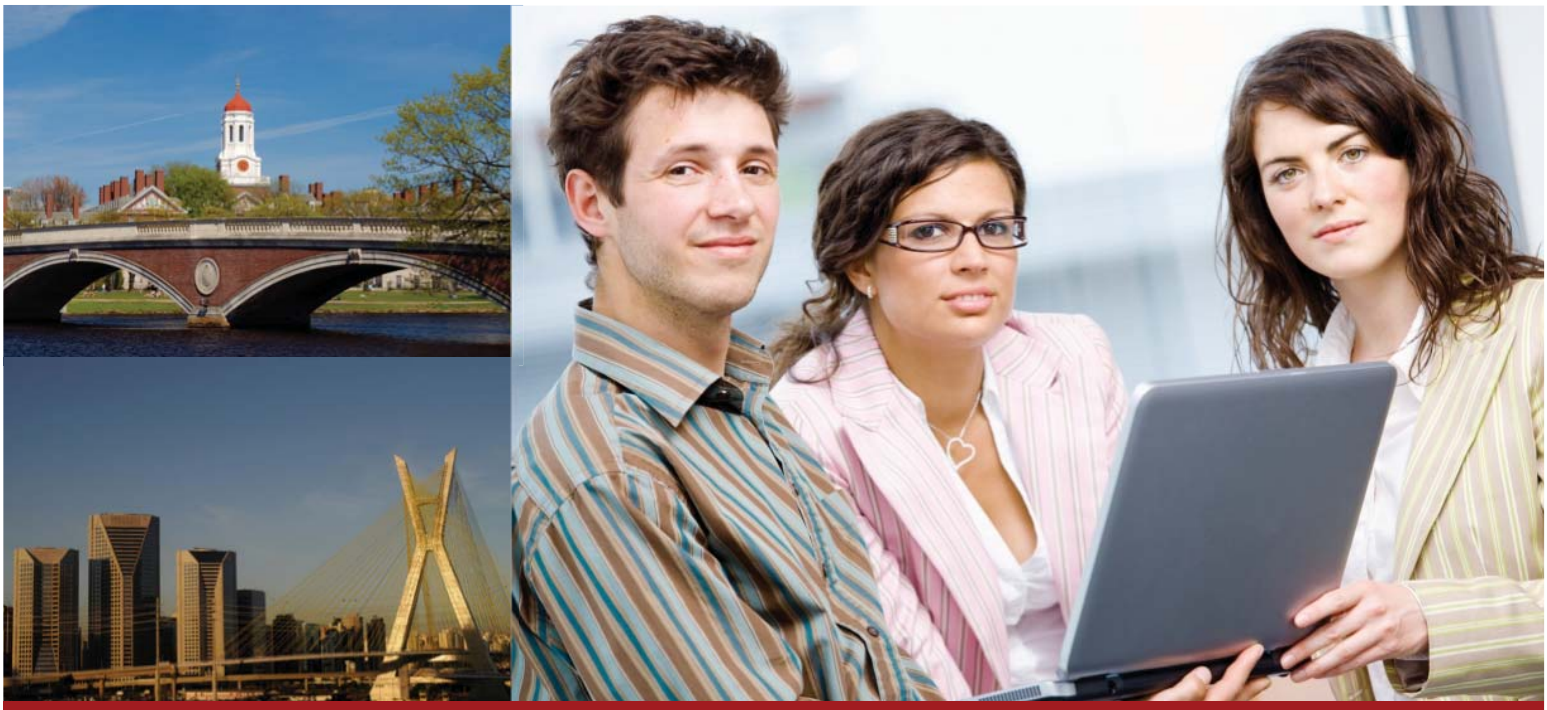
Course Director: **Felipe Fregni, MD, PhD, MPH**
Associate Professor, Harvard Medical School

February – November 2013

Kendall Square Center – Cambridge, MA

What You Can Expect

The collaborative distance-learning program in Clinical Research is offered to participants from Boston and throughout the world. This 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. Participants can earn up to 72 (or 145.5 with all of the available optional workshops) *AMA PRA Category 1 credits™.*



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Principles and Practice of Clinical Research

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).

LEARNING 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. 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 4-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 in an effective manner, collect data properly, use the basic functions of a statistical software package, choose appropriate basic statistical tests, critically read and understand a research paper, understand basics of article publication and review.

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).

Course Site: 245 First Street, Riverview II, 18th Floor, Cambridge, MA, 02142

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.

COURSE DATES:

Distance Learning:	February - November 2013
Optional 4-Day Workshop:	October 24-27, 2013
Optional 2-Day Statistical Workshop in Boston:	July 18-19, 2013
Optional 2-Day Study Coordinator Workshop:	July 15-16, 2013

COURSE TUITION FEES (all registration prices include a 1-year Small Stata 12 (GradPlans™) license):

6 Mos Main Course + 4-Day Workshop + book + 2-Day Stats Workshop + 2 Day Research Coor	$10,000.00
6 Month Main Course + 4-Day On-Site Workshop + book + 2-Day Statistical Workshop	$8,500.00
6 Month Main Course + 4-Day On-Site Workshop + book	$7,000.00
6 Month Main Course + 4-Day On-Site Workshop	$6,750.00
6 Month Main Course + book	$5,550.00
6 Month Main Course	$5,250.00
Residents and Fellows 6 Month Main Course + book	$3,000.00
Resident and Fellows 6 Month Main Course	$2,750.00
Clinical Research Fellow Practice Workshop	$2,750.00
4-Day On-Site Workshop	$1,500.00
2-Day Statistical Workshop	$1,500.00
2-day Study Coordinator Workshop	$1,500.00

APPLICATION AND COURSE ADMISSION:
Registration is limited. Please submit the following documents online: Curriculum Vitae and letter of intent stating the reason to participate in the course. Application is due by January 5, 2013. Late application will be considered on a case-by-case basis.

INTERNATIONAL SITES AND CONTACTS:

USP – São Paulo, Brazil:
Dr. Wu Tu Hsing
wu@fmusp.org.br
ISPRM – International site:
Dr. Marta Imamura
martaimf@gmail.com

UNICAMP – Campinas, Brazil:
Dr. Heitor Moreno Junior
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ABC – São Paulo, Brazil:
Dr. Auro del Giglio
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Dr. Daniel Cubero
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Mackenzie – São Paulo, Brazil:
Dr. Paulo Sérgio Boggio
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Uberlandia – Minas Gerais
Dr. Roberto Botelho
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Instituto Etica – Salvador, Bahia: *Dr. Juleilda Nunes*
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UFRGS – Porto Alegre, Brazil:
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USMP – Lima, Peru:
Dr. Tamara Jorquiera
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tjorquiera@usmp.edu.pe
Dr. Christian Acosta Villegas
christian_nr@hotmail.com

Universidad de Cuenca – Cuenca, Ecuador:
Dr. Arturo Carpio
arturo.carpio@ucuenca.edu.ec

Coimbra University Hospital – Coimbra, Portugal:
Dr. Pedro Monteiro
pedromontei@gmail.com

Carus – Dresden, Germany:
Dr. Timo Siepmann
siepmann@ppcr.hms.harvard.edu

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

Please visit www.ppcr.hms.harvard.edu or contact
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Program Schedule 2013

6-month Main Course Component (via live site center or live webcast):

Module One – Basics of Clinical Research:

Tutorial Lecture - 21 February, 2013: Course Staff and Course Director
Opening Remarks

Lecture 1 - 14 March 2013: Steve Freedman
Introduction to Clinical Trials

Lecture 2 – 21 March 2013: Jonathan Williams
Selection of the Questions

Lecture 3 – 28 March 2013: Felipe Fregni
Study Population

Lecture 4 - 04 April 2013: David Wypij
Basic Study Design

Online discussion: Ethical and regulatory issues

Lecture 5 – 11 April 2013: Joseph Massaro
Study Blinding

Lecture 6 – 18 April 2013: David Wypij
The Randomization Process

Lecture 7 - 25 May 2013: Priscilla Driscoll-Schempp
Recruitment of Study Participants
Lotfi Merabet
Participant Adherence

Module Two – Statistics:

Lecture 8 - 09 May 2013 - Roger Davis
Statistics - Basics

Clinician Statistical Corner - Munir Boodhwani
Data classification and Sample Size Calculation in Clinical Research

Lecture 9 - 16 May 2013: Felipe Fregni
Statistical Tests I

Lecture 10 - 23 May 2013: Felipe Fregni
Statistical Tests II

Lecture 11 - 30 May 2013: Jessica Paulus
Sample Size

Lecture 12 - 06 June 2013: Roger Davis
Survival Analysis

Lecture 13 – 13 June 2013: Felipe Fregni
Other Issues in Statistics I

Lecture 14 - 20 June 2013: Felipe Fregni
Other Issues in Statistics II

Module Three – Practical Aspects of Clinical Research:

Lecture 15 – 27 June 2013: Gretchen Brodnicki
Integrity in Research

Lecture 16 – 15 August 2013: Dennis LaCroix
The Business of Clinical Research
Vera Novak
Being a Clinical and Translational Scientist

Lecture 17 - 22 August 2013: Alan Zaslavsky
Design and Analysis of Surveys

Lecture 18 - 29 August 2013: John Ferguson
Assessing risk and adverse effects in clinical research
Suzanne George
Phase III and Multicenter Trials

Lecture 19 – 05 September 2013: Caren Solomon
Manuscript submission

Module Four – Study Design:

Lecture 20 - 12 September 2013: Jessica Paulus & Felipe Fregni
Special Panel: RCT vs. Observational Designs – how to choose?

Lecture 21 - 19 September 2013: Clarissa Valim
Observational Studies

Lecture 22 - 26 September 2013: Laura Mauri
Confounders in observational studies: using the method of propensity score

Lecture 23 - 03 October 2013: Richard Kuntz
Other Designs

Lecture 24 – 10 October 2013: Scott Evans
Non-inferiority designs

Final Exam will be scheduled in November after the 4-Day On-Site intensive course.

Optional 2-Day Statistical Workshop, Boston:

Thursday, July 18, 2013

Correlation and Causality

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

Linear Regression

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

Friday, July 19, 2013

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

ANOVA

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

Other Issues Related to Regression Modeling

3:15pm – 4:00pm	Interaction and Quadratic Effects
4:00pm – 5:00pm	Regression Modeling in Practice

ACCREDITATION: The Harvard Medical School (HMS) 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 145.5 *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 72 *AMA PRA Category 1 Credits™*
Optional Clinical Research Fellow Workshop: A maximum of 10.5 *AMA PRA Category 1 Credits™*
Optional 2-day STATS workshop: A maximum of 15 *AMA PRA Category 1 Credits™*
Optional 4-day BRAZIL workshop: A maximum of 31.75 *AMA PRA Category 1 Credits™*
Optional 2-day Study Coordinator workshop: A maximum of 16.25 *AMA PRA Category 1 Credits™*

This course is designed to meet the following ACGME competencies: Medical Knowledge, Practice-based Learning and Improvement and Professionalism.

FACULTY:

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

Munir Boodhwani, MD, MMSc
(University of Ottawa)

Gretchen Brodnicki, JD
(Harvard Medical School)

Merit Cudkowicz, MD
(Harvard Medical School)

Roger Davis, ScD
(Harvard School of Public Health)

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)

Donald Halstead
(Harvard School of Public Health)

Christine Jesser, PhD
(Harvard School of Public Health)

Richard Kuntz, MD
(Harvard Medical School)

Joyce A. Sutcliffe, PhD
(Tetraphase Pharmaceuticals)

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)

Jonathan S. Williams, MD
(Harvard Medical School)

Catherine E. Sutherland,
(Harvard Medical School)

Priscilla Driscoll-Schempp, MD
(Harvard Clinical Research Institute)

Shelley Tworoger, PhD
(Harvard School of Public Health)

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Program Schedule 2013

Optional 4-Day Workshop (location to be determined):

THURSDAY, OCTOBER 24, 2013

7:00am – 8:00am	Registration
8:00am – 8:15am	Welcome!
8:15am – 9:00am	Bias - Lotfi Merabet
9:00am – 9:45am	Randomization – Jessica Paulus
9:54am – 10:00am	Break
10:00am – 12:00am	Small Group Discussion
12:00am – 1:00pm	Lunch
1:00pm – 2:00pm	Office Hours with Speakers
2:00pm – 5:00pm	Small Group Discussions
5:00pm – 6:00pm	Closing Remarks and Evaluations

FRIDAY, OCTOBER 25, 2013

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

SATURDAY, OCTOBER 26, 2013

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

SUNDAY, OCTOBER 27, 2013

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

The optional 4-day live intensive course will host eight to 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.

Participating International Sites:

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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Program Schedule 2013

Optional Study Coordinator Workshop, Boston

MONDAY, JULY 15, 2013

07:00am – 08:00am Registration
08:00am – 08:15am Welcome
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: students will be divided in groups and choose sites and negotiate agreements with mock sites
12:00am – 01:00pm Lunch
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 Group discussion

TUESDAY, JULY 16, 2013

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 – 12:00am Practical exercises II: students will be divided in groups and define strategies to manage trials
12:00am – 01:00pm Lunch
01:00pm – 02:00pm Management and leadership in clinical research
02:00pm – 05:00pm Final project presentation and group discussion.

About the Course:
The 2-day live intensive course will host five Harvard professors 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.

FACULTY/SPEAKERS

Felipe Fregni, MD, PhD, MPH
(Harvard Medical School)
Lotfi Merabet, OD, PhD
(Harvard Medical School)
Lauren Dewey Platt, PhD
(Harvard Medical School)
Priscilla Driscoll-Schempp, MD
(Harvard Clinical Research Institute)
Catherine E. Sutherland, CIP
(Harvard Medical School)

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Program Schedule 2013

Optional Clinical Research Fellow Practice Workshop, Boston

Meeting 1 MARCH 28, 2013	**(7:00pm - 8:30pm)**	**Welcome and general instructions**
Meeting 2 APRIL 25, 2013	**(7:00pm - 8:30pm)**	**10 minute presentation of project and proposal review**
Meeting 3 MAY 30, 2013	**(7:00pm - 8:30pm)**	**Practical challenges in clinical research**
Meeting 4 JUNE 27, 2013	**(7:00pm - 8:30pm)**	**Presentation of data and mid-course evaluation**
Meeting 5 AUGUST 29, 2013	**(7:00pm - 8:30pm)**	**Update of projects**
Meeting 6 SEPTEMBER 26, 2013	**(7:00pm - 8:30pm)**	**Setting up a laboratory and future career opportunities**
Meeting 7 OCTOBER 31, 2013	**(7:00pm - 8:30pm)**	**Mentoring in clinical research**
Meeting 8 DECEMBER 12, 2013	**(7:00pm - 8:30pm)**	**Final presentation of projects and review papers and final evaluation**

About the Course:

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 Harvard-affiliated laboratory as a research fellow and develop in parallel a project based on their practical laboratory experience. We will assist with placement in Harvard-affiliated laboratories, but the final decision for acceptance in the Harvard- affiliated 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.

FACULTY/SPEAKERS

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

Vera Novak, MD, PhD
(Harvard Medical School)

Lotfi Merabet, OD, PhD
(Harvard Medical School)

Donald Halstead
(Harvard School of Public Health)

Jennifer Gardner EdM, Higher Education Administrator
(Harvard Graduate School of Education)

Emmanuel Coronel, MD
(University of Miami/Jackson Memorial Hospital)

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