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. Participants can earn up to 72 (or 145.5 with all of the available optional workshops) AMA PRA Category 1 Credits™.
Description
Clinical research is critically important for advancements in medicine; however its implementa-
tion is still immature in most of the medical specialties. In addition, many clinicians cannot evalu-
ate 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 ques-
tion, select study population, randomization and blinding methods), statistical methods (data dis-
tribution 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. Par-
ticipants 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 lec-
tures 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 statisti-
cal 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 in an effective manner,
collect data appropriately, use the basic functions of a statistical software package, choose ap-
propriate 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 micro-
phone. Site centers must be equipped with videoconference technology and have technicians
available.

INTERNATIONAL SITES AND CONTACTS
USP – São Paulo, Brazil
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Vitoria, Brazil
Ester Miyuki Nakamura-Palacios, MD
emppalacios@gmail.com

* 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 – 20 February, 2014: Course Director and Staff
Opening Remarks

Lecture 1 - 13 March 2014: Steve Freedman  
Introduction to Clinical Trials

Lecture 2 – 20 March 2014: Jonathan Williams  
Selection of the Questions

Lecture 3 – 27 March 2014: Michele Hacker  
Study Population

Lecture 4 - 03 April 2014: David Wypij  
Basic Study Design

Online discussion: Ethical and regulatory issues

Lecture 5 – 10 April 2014: Joseph Massaro  
Study Blinding

Lecture 6 – 17 April 2014:  
Priscilla Driscoll-Schempp  
Recruitment of Study Participants & Lotfi Merabet  
Participant Adherence

Lecture 7 – 24 April 2014: David Wypij  
The Randomization process

**Module Two**  
Statistics

Lecture 8 - 08 May 2014: Roger Davis  
Statistics - Basics

Lecture 9 – 15 May 2014: Felipe Fregni  
Statistical Tests I

Lecture 10 - 22 May 2014: Felipe Fregni  
Statistical Tests II

Lecture 11 - 29 May 2014: Felipe Fregni  
Other Issues in Statistics I

Lecture 12 - 05 June 2014: Roger Davis  
Survival Analysis

Lecture 13 – 12 June 2014: Felipe Fregni  
Other Issues in Statistics II

Lecture 14 - 19 June 2014: Jessica Paulus  
Sample Size

**Module Three**  
Practical Aspects of Clinical Research

Lecture 15 – 26 June 2014:  
Kristin Bittinger  
Integrity in Research & Suzanne George  
Phase III and Multicenter Trials

6-Week Statistical Study Period

Lecture 16 – 14 August 2014:  
Riekie de Vet  
Development of a Measurement Instrument & Alan Zaslavsky  
Design and Analysis of Surveys

Lecture 17 - 21 August 2014: John Ferguson  
Assessing risk and adverse effects in clinical research

Lecture 18 - 28 August 2014:  
Karen Lodigiani & Jennifer Meneses  
The Business of Clinical Research – Negotiating contracts & Donald Halstead  
Manuscript Writing

Lecture 19 – 04 September 2014: Caren Solomon  
Manuscript submission

**Module Four**  
Study Designs

Lecture 20 - 11 September 2014: Scott Evans  
Non-inferiority designs

Lecture 21 - 18 September 2014: Richard Kuntz  
Other Designs

Lecture 22 – 25 September 2014: Clarissa Valim  
Observational Studies

Lecture 23 - 02 October 2014: Robert Yeh  
Confounders in observational studies: using the method of propensity score

Lecture 24 – 09 October 2014: Shelley Tworoger & Felipe Fregni  
Special Panel: RCT vs. Observational Designs – how to choose?

**DISCLOSURE POLICY**

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# Application and Course Admission

Registration is limited. Please submit the following documents online at [www.ppcr.hms.harvard.edu/registration](http://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, 2013.** Late application will be considered on a case-by-case basis.

## Course Dates

<table>
<thead>
<tr>
<th>Course Component</th>
<th>Dates</th>
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</thead>
<tbody>
<tr>
<td>9-Month Distance Learning Main Course Component</td>
<td>February - November 2014</td>
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<tr>
<td>Optional 5-Day Workshop</td>
<td>October 22-26, 2014</td>
</tr>
<tr>
<td>Clinical Research Fellow Practice Workshop</td>
<td>February - December 2014</td>
</tr>
<tr>
<td>Optional 2-Day Study Coordinator Workshop</td>
<td>July 14-15, 2014</td>
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<tr>
<td>Optional 2-Day Statistical Workshop</td>
<td>July 17-18, 2014</td>
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<tr>
<td>Optional Introductory Workshop and Evidence-Based Medicine</td>
<td>March 11, 2014</td>
</tr>
</tbody>
</table>

## Course Tuition Fees

All registration prices include a 1-year Small Stata 12 (GradPlansTM) license.

<table>
<thead>
<tr>
<th>Course Package</th>
<th>Fee</th>
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<tbody>
<tr>
<td>9-Month Main Course + 5-Day Workshop + 2-Day Stats Workshop + 2 Day Research Coord Workshop + Introductory Workshop and Evidence-Based Medicine + Book</td>
<td>$9,950.00</td>
</tr>
<tr>
<td>9-Month Main Course + 5-Day On-Site Workshop + 2-Day Statistical Workshop + book</td>
<td>$8,500.00</td>
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<tr>
<td>9-Month Main Course + 5-Day On-Site Workshop + book</td>
<td>$7,000.00</td>
</tr>
<tr>
<td>9-Month Main Course + 5-Day On-Site Workshop</td>
<td>$6,750.00</td>
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<tr>
<td>9-Month Main Course + book</td>
<td>$5,550.00</td>
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<tr>
<td>9-Month Main Course</td>
<td>$5,250.00</td>
</tr>
<tr>
<td>Residents and Fellows 9-Month Main Course + book</td>
<td>$3,500.00</td>
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<tr>
<td>Resident and Fellows 9-Month Main Course</td>
<td>$3,250.00</td>
</tr>
<tr>
<td>9-Month Main Course – Residents &amp; PhD Students Groups (minimum of 10 participants)</td>
<td>$2,750.00</td>
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<tr>
<td>Clinical Research Fellow Practice Workshop</td>
<td>$2,750.00</td>
</tr>
<tr>
<td>5-Day On-Site Workshop</td>
<td>$1,500.00</td>
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<tr>
<td>2-Day Statistical Workshop</td>
<td>$1,500.00</td>
</tr>
<tr>
<td>2-Day Study Coordinator Workshop</td>
<td>$1,500.00</td>
</tr>
<tr>
<td>Introductory Workshop and Evidence-Based Medicine</td>
<td>$750.00</td>
</tr>
</tbody>
</table>
5-DAY WORKSHOP

The optional 5-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 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.

Wednesday, October 22, 2014

International Clinical Research Forum (students will present their Research projects as poster presentation and the best ones will be chosen for oral presentation)

12:00pm Registration
12:30pm Introduction and opening – Felipe Fregni
01:00pm – 2:30pm Oral presentations
02:30pm – 3:30pm Poster Presentations
03:00pm – 04:30pm Oral Presentations
04:30pm Wrap up – Felipe Fregni

Opening of 5-Day Workshop

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

Thursday, October 23, 2014

08:00am – 08:45am Lecture – special topic I – Jessica Elder
08:45am – 12:00pm Small Group Discussions
12:00pm – 04:00pm Break
03:00pm – 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

Friday, October 24, 2014

08:00am – 08:45am Lecture – special topic II – Roger Davis
08:45am – 12:00pm Small Group Discussions
12:00pm – 04:00pm Break
03:00pm – 04:00pm Real life Statistics I – Clarissa Valim (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 II – Donald Halstead
08:00pm – 09:00pm Break
09:00pm – 11:00pm Celebration and Awards with dinner

Saturday, October 25, 2014

08:00am – 08:45am Lecture – special topic III – Jessica Paulus
08:45am – 12:00pm Small Group Discussions
12:00pm – 04:00pm Meeting for 2013 participants interested in being PPCR 2014 TAs
03:00pm – 04:00pm Real life Statistics I – Clarissa Valim (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

Sunday, October 26, 2014

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 group projects will be awarded a special certificate)
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 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.

Meeting 1 - March 27, 2014
7:00pm - 8:30pm Welcome and general instructions

Meeting 2 - April 24, 2014
7:00pm - 8:30pm 10 minute presentation of project and proposal review

Meeting 3 - May 29, 2014
7:00pm - 8:30pm Practical challenges in clinical research

Meeting 4 - June 26, 2014
7:00pm - 8:30pm Presentation of data and mid-course evaluation

Meeting 5 - August 28, 2014
7:00pm - 8:30pm Update of projects

Meeting 6 - September 25, 2014
7:00pm - 8:30pm Setting up a laboratory and future career opportunities

Meeting 7 - October 30, 2014
7:00pm - 8:30pm Mentoring in clinical research

Meeting 8 - December 11, 2014
7:00pm - 8:30pm Final presentation of projects and review papers and final evaluation

FACULTY/SPEAKERS
Felipe Fregni, MD, PhD, MPH, MEd
Harvard Medical School
Lotfi Merabet, OD, PhD
Harvard Medical School
Ivan Rosas, MD
Harvard Medical School
Leon Morales Quezada, MD
Spaulding Rehabilitation Hospital

www.ppcr.hms.harvard.edu  |  info@ppcr.hms.harvard.edu  |  617-952-6154 USA
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 14, 2014
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
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 15, 2014
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 – 01:00pm Lunch
01:00pm – 03:00pm Final project presentation and group discussion

FACULTY
Felipe Fregni, MD, PhD, MPH, MEd
Associate Professor of Neurology, Harvard Medical School, Associate Professor of PM&R, Harvard Medical School
Director, Clinical Trials Network, Beth Israel Deaconess Medical Center
Lotfi Merabet, OD, PhD
Associate Director, Visual Rehabilitation Center, Massachusetts Eye and Ear Infirmary; Assistant Professor of Ophthalmology, Harvard Medical School
Kathryn E. Hall, MS, RNCS, ANP-BC
Nursing Director, Clinical Research Center, Massachusetts General Hospital
Jennifer Buell, Ph.D.
Senior Director of Clinical Project Management, Harvard Clinical Research Institute
Ian Shemp, MA
Senior Project Manager, Surgical ICU Translational Research (STAR) Center, Brigham and Women's Hospital
Leslie Howes, MPH, CIP
Director of Quality Improvement Program, Office of Human Research Administration, Harvard School of Public Health
Erica Sorrentino, MA
Senior Clinical Research Coordinator, Cantor Center, Dana Farber Cancer Center
Opeyemi Talabi-Oates, MBA
Manager of CCI Study Coordinator Core, Clinical Trials Center, Brigham and Women's Hospital
Malarick, Charlene, R.N, BSN, CCRP
Senior QA/QI Specialist, Human Research Quality Improvement Program, Partners Health Care
Lynn A. Sympon, MPH
Research Data & Analytics Services Manager, Harvard Catalyst | The Harvard Clinical and Translational Science Center, Partners HealthCare | Research Computing, ERIS
Linda Godfrey-Bailey, MSN, ACNS, BC
Nurse Director and Clinical Research Coordinator, Beth Israel Deaconess Medical Center
Cindy Williams, MSN, RN, PNP
Nurse Research Coordinator, Harvard Catalyst Center, Children's Hospital Boston

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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 18, 2014

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

07:00am – 08:00am Registration
08:00am – 08:15am Welcome!
08:15am – 09:00am 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 – 5:00pm Simple Linear Regression
05:00pm – 6:00pm Multiple Linear Regression

Friday, July 19, 2014

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

07:00am – 08:00am Breakfast
08:00am – 09:00am Logistic Regression
08:00am – 09:00am Correlation and Causality
09:00am – 09:45am Statistical Tests
09:45am – 10:00am Break
10:00am – 11:00am Practical Applications
12:00am – 01:00pm Lunch

Logistic Regression

11:00am – 12:00am Assumptions for Using Logistic Regression
12:00am – 1:00pm Lunch
1:00pm – 2:00pm Logistic Regression Model Building
2:00pm – 3:00pm Assessing Model Fit
3:00pm – 3:15pm Break
3:15pm – 4:00pm Interaction and Quadratic Effects
4:00pm – 5:00pm Regression Modeling in Practice
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.

Tuesday, March 11, 2014

Study Activities

- 07:30am – 08:00am Registration
- 08:00am – 08:45am Goals and expectations of Principles and Practice of Clinical Research
- 08:45am – 09:00am Students Introduction and brief presentation
- 09:00am – 09:50am History of Scientific Investigation
- 09:50am – 10:40pm Why Evidence-Based Medicine
- 10:40pm – 11:30pm Clinician vs. Researcher perspective in Evidence-Based Medicine
- 11:30pm – 01:00pm Lunch
- 01:00pm – 01:40pm Methods of access and databases of medical/research information
- 01:40pm – 02:30pm How to assess medical evidence

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Harvard Medical School
Ivan Rosas, MD
Harvard Medical School
Erica Camargo, MD
Massachusetts General Hospital
Donald Halstead
Harvard School of Public Health